Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

April 28, 2009

MEDICAL CONSULTANTS INTL. LTD.
59 OXFORD PLACE
GLEN ROCK NEW JERSEY 07452

Re: Premarket Notification Number: K903654

Dear Manufacturer:

The Food and Drug Administration (FDA) is currently in the process of evaluating the classification of class III devices that are currently marketed through clearance of a premarket notification (510(k)) submission. These devices were found to be substantially equivalent to a preamendments class III device type for which no date has yet been established for requiring the submission of a premarket approval application (PMA). (A class III preamendments device type is a device type that was legally on the market before May 28, 1976, and that was subsequently classified into class III.) FDA premarket notification (510(k)) records indicate that you received clearance to market a device belonging to one of the class III device types being evaluated. Accordingly, FDA is requesting that you submit specific information, discussed below, to support these classification efforts. These classification efforts will culminate in a decision either to call for a PMA for these class III devices, or to reclassify these devices into Class II (special controls) or Class I (general controls). FDA will reach this decision based on all available and reviewed information pertaining to each device type. For certain device types, classification panel hearings may be held to assist in these efforts. Any future proposed decisions will apply to the device type as a whole, not solely to your individual device.

As stated, FDA, in accordance with Section 515(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. § 360e(i)), is requiring manufacturers who were marketing, or have clearance to market through a 510(k) substantial equivalence decision, the class III device types referenced above as of April 9, 2009, to submit certain information. The enclosed Federal Register notice details the specific device types, the requested information, and the submission instructions. You are required to submit this information by August 7, 2009, to:

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD, 20852.

Please note that items posted to this docket will be redacted in accordance with the Freedom of Information Act (FOIA) (5 U.S.C. § 552), and posted to the docket. To ensure your posted documents are redacted, prior to posting, please denote submissions uploaded to the docket as such by typing the following words in the top of the *"General Comments"* box: *"CONFIDENTIAL MATERIAL DO NOT POST TO THE WEB AS REQUESTED BY SUBMITTER. STATUS SHOULD BE CONFIDENTIAL."*

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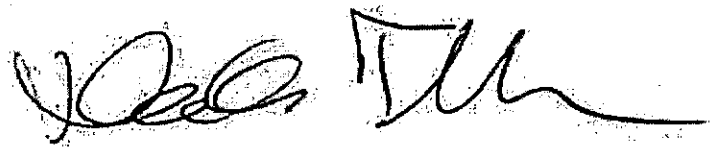
If you have information showing that you have received this letter in error, or that our records supporting this letter are inaccurate, such that you are relieved of the obligation to submit the requested information, please send an explanation of the error, noting your 510(k) number, to:

Attn.: 510(k) Staff, 515(i) Submission
Document Mail Center, HFZ-401
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD, 20850

Please note that in lieu of submitting the above requested information, you may also petition FDA to reclassify the device type in accordance with Section 513(e) of the act (21 U.S.C. 360c(e)) and our regulations found in 21 CFR Part 860. In general, FDA's review of reclassification petitions can be completed more efficiently when manufacturers collaborate and submit a single reclassification petition that includes all relevant and accurate information for the given device type. This collaboration can be organized by contacting other manufacturers of the pertinent device through either a professional association or other affiliation.

Additional information or inquiries relevant to this classification mandate can be obtained by referencing the FDA Class III website at: http://www.fda.gov/cdrh/classiii.html, or by contacting Sarah K. Morabito at (240) 276-3975.

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

OCT - 4 1990

Saul Liss
President
Medi Consultants, Inc.
59 Oxford Place
Glen Rock, New Jersey 07452

Re: K903654
Liss Cranial Stimulator Model SBL202-B
Regulatory Class: III
Dated: July 2, 1990
Received: July 6, 1990

Dear Mr. Liss:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

Your device is classified into class III (Premarket Approval). Class III devices will be required to undergo premarket approval at some time in the future. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

In our review of your submission, we noted that your device may violate the misbranding provisions of the law. The Food and Drug Administration's Neurological Devices Classification Panel has reported that the efficacy of cranial electrotherapy stimulation has not been established by well-controlled studies and that more investigation in this area is needed. Therefore, claims of effectiveness of your device for relief of anxiety, insomnia, and depression may cause your device to be misbranded. Before marketing your device, we strongly recommend that you consult with the Division of Compliance Operations concerning the labeling for your device to avoid a possible violations.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

David L. West, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices
and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

OCT - 4 1990

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President
Medi Consultants, Inc.
59 Oxford Place
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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ 430	MORRIS	9/14	2430		9/26	342		10/3/90
3		9/20	430		9/28/90	404		10/3/90
HFZ-430		9/25/90	323		10/3/90	464		10/4/90

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FDAINFO@fda.hhs.gov or call 301-796-8118

3

*U.S. GPO: 1989-619-669

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An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

David L. West, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices
and Radiological Health

cc: HFZ-401 (DMC)
HFZ-400 (ODE)
HFZ-402 (RChissler)
HFZ-430 (DANRD)
HFR-MA300

JMMorris:NE/510K #40
Draft:crd/9/13/90
Final:crd/9/13/90
Proofread:
Decspell:crd/9/13/90

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8...

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date . SEPTEMBER 25, 1990

From REVIEWER(S) - NAME(S) J. M. MORRIS

Subject 510(k) NOTIFICATION K903654

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

✓ (A) Is substantially equivalent to marketed devices. (b)(4) [redacted]

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

_____ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

(b)(4) [redacted]

The submitter requests under 21 CFR §807.95:

_____ No Confidentiality

✓ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

84 JXK Class III

Additional Product Code(s) w/Panel (optional):

CRANIAL ELECTRICAL STIMULATOR

REVIEW: _____ 9/17/90 (BRANCH CHIEF) _____ 9/25/90 (DATE)

FINAL REVIEW: _____ 9/26/90 (DIVISION DIRECTOR) (DATE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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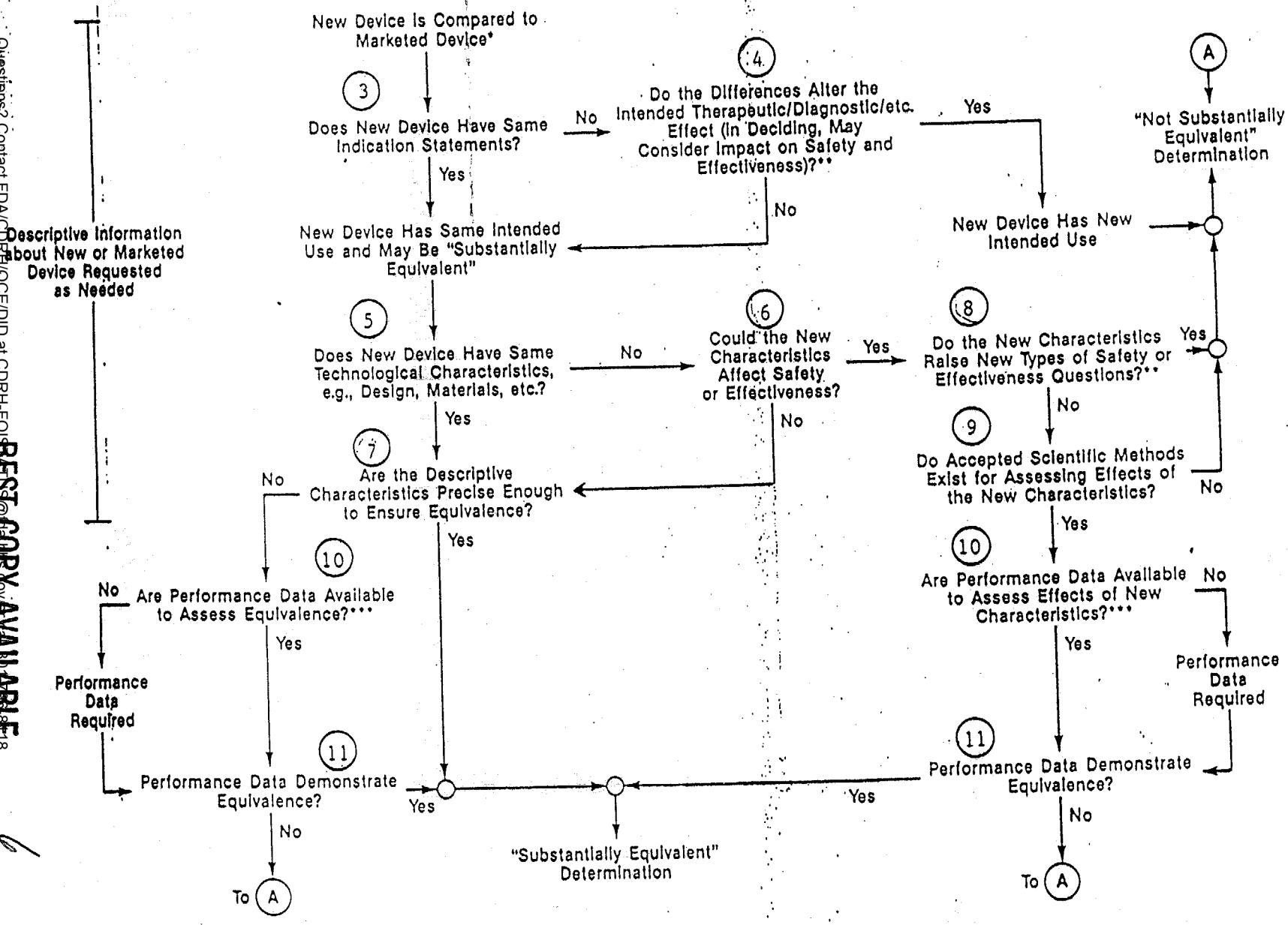
5

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) ... sions Compare New Devices to Marketed Devices. FDA Requests ... ormation If the Relationship Between Marketed and "Predicate" ... Add...

** This ... n Is Normally Based on Descriptive Information Alone, But ... Lim... ng Information Is Sometimes Required. ... In the 510(k), Other 510(k)'s, The Center's Classification Files, or the Literature.

*** Dat...

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@fda.hhs.gov 18.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

AUGUST 15, 1990

MEDI CONSULTANTS, INC.
ATTN: SAUL LISS
59 OXFORD PLACE
GLEN ROCK, NJ 07452

D.C. Number : K903654
Received : 07-06-90
90th Day : 10-04-90
Product : MEDI MODEL SBL202-B

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8113.

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K 903654 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: J. Morris DIVISION/BRANCH: DANRD/NDBO

TRADE NAME: MEDI Model SBL202-B COMMON NAME: Liss Cranial Stimulator

PRODUCT TO WHICH COMPARED: Cranial Electrotherapy Stimulator, Neuro Systems, Inc.
(510(k) NUMBER IF KNOWN) Other 510Ks: K894515, K894097, K883812.

	YES	NO	
1. IS PRODUCT A DEVICE?	✓		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	✓		- IF NO STOP
3. SAME INDICATION STATEMENT?	✓		- IF YES GO TO 5
(4.) DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	✓		- IF YES GO TO 7
(6.) COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	✓		- IF NO GO TO 10 - IF YES STOP - SE
(8.) NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10. PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DAT
(11.) DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
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510(k) Review

K 903654

Company: MEDI Consultants, Inc.

Device Proprietary Name: MEDI Model SBL202-B

1. Is this device life-supporting or life-sustaining? no

2. Is this an implanted device (short-term or long-term)? no

3. If device incorporates a microprocessor, does the firm certify that testing has shown that shows all system requirements are fulfilled and that software changes will require retesting before release? Estimated level of concern is: (Major, Moderate, Minor).

no

4. Subject device can be compared to (prior devices): Neurotone 101, NeuroSystems, Inc. (device name, manufacturer)
MEDI Model SBL201-M, MEDI Consultants, Inc. (K894515)
NTI-1000, Neurotek, Inc. (K894097)
Health Pax HP-1, Health Directions, Inc (K883812)

5. Submission provides: comparative specifications? yes

bench test or in vitro data? *yes animal test data? no

clinical data? no ref. to industry stds? no

6. SUMMARY (device characteristics; differences between device and preenactment (predicate) devices; new intended use; new technology and new kinds of safety issues):

* see attached summary sheet
(bench test data refers to the waveform analysis)

7. RECOMMENDATION:

I believe that this device is equivalent to: 84 JXK
(panel & product codes)

Classification should be based on: 882.5800
(CFR Section # and device name)

Cranial Electrotherapy Stimulator presently class: III

Janice M. Morris 9/14/90
(signed, date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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510k REVIEW
SUPPLEMENTAL SUMMARY SHEET

510K NUMBER: K903654
MANUFACTURER: MEDI Consultants, Inc.
DEVICE NAME: LISS Cranial Electrotherapy Stimulator, Model SBL202-B

SUMMARY:

The LISS Cranial Stimulator has the intended use to reduce the symptoms of depression, anxiety, and insomnia. This device has the same characteristics as the MEDI CES Model SBL201-M (K894515B) submitted earlier on February 2, 1990, except for the electronic waveform. This version involves essentially the same positive modulating signal as before followed by an equal and opposite negative signal. (b)(4)

(b)(4)

[redacted]

Prescription legend is provided in the Caution labeling. Precautions and Adverse Reactions are mentioned in the device instruction manual. Electrodes used are water/wet sponge type and are supplied with the device.

Cranial Electrotherapy Stimulator devices are preamendment class III devices. This file contains no valid scientific data supporting the claim that this device relieves the symptoms of depression, anxiety, and insomnia. The Neurological Devices Classification Panel concluded that CES has not been shown effective in treating these conditions, therefore, the LISS Cranial Stimulator may be misbranded. Reference FR vol. 43 no. 229, 11/28/78, pp. 55716-55717.

Janine M. Morris 9/17/90

Janine M. Morris, Mechanical Engineer
Division of Anesthesiology, Neurology,
and Radiology Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SAMPLE WAVEFORM ANALYSIS FOR LISS CES MODEL SBL202-B (K903654)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Waveform Analysis

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Questions? Contact FDA/CDRH/OSE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-5611

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SAMPLE WAVEFORM ANALYSIS FOR LISS CES MODEL SBL201-M (K894515)
(PREVIOUS 510K SUBMISSION)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (301) 796-9718

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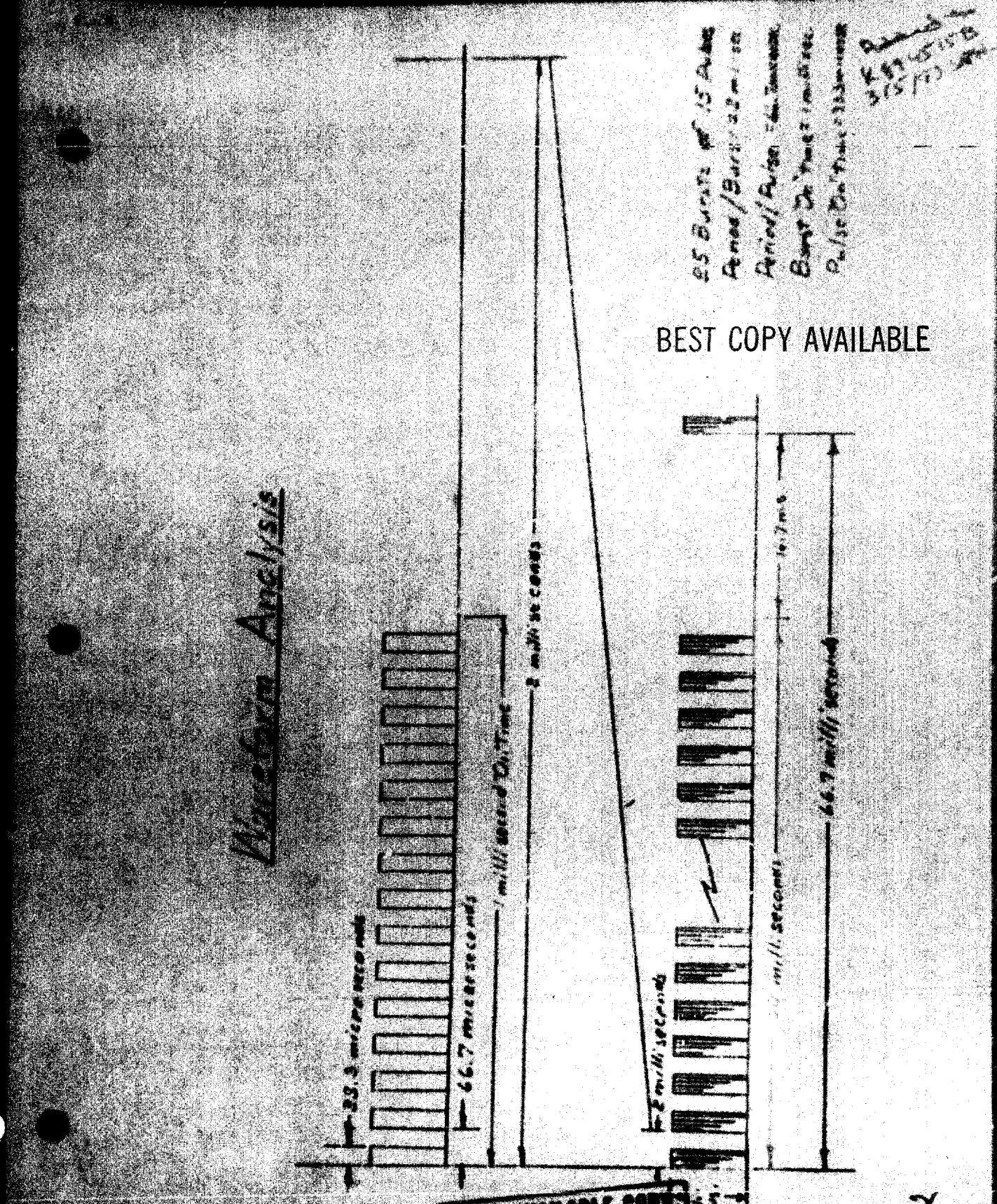

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Questions? Contact FDA/CDRH/OCE/DID at OIDP@cdrh.fda.hhs.gov or call 301-796-8118.

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MEDI CONSULTANTS, INC.

K903654

July 2, 1990

Office of Device Evaluation
510 (K) Document Mail Center (HFZ-401)
Center for Devices & Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

RECEIVED
6 Jul 90 07 8
FDA/CDRH/ODE/DMC

Re: Notice of 510 (k) Premarket Notification (LISS Cranial Stimulator [Zero DC])

Gentlemen:

In accordance with Section 510 (k) of the Federal Food, Drug and Cosmetic Act, and in conformance with Title 21 of Federal Regulations Part 807, this premarket notification is being submitted 90 days prior to the date on which MEDI Consultants, Inc. proposes to introduce into interstate commerce a Cranial Electrotherapy Device to be known as the LISS Cranial Stimulator Model [Zero DC] SBL202-B.

The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name: Cranial Electrotherapy Stimulator

   Common/Usual Name: LISS Cranial Stimulator [Zero DC]

   Trade/Proprietary Name: MEDI Model SBL202-B

2. Establishment Registration Number

MEDI Consultants, Inc. has submitted Form 2891 (Initial Registration of Medical Device Establishment) for its manufacturing facility located at 59 Oxford Place, in Glen Rock, New Jersey 07452). The facility is now located at 175 Rock Road in Glen Rock, New Jersey 07452-1724.

3. Classification

The Cranial Electrotherapy Stimulator is equivalent in performance to equipment which was in commercial distribution, preamendment (May 28,1976). Please note appendices describing preamendment device, Neurotone 101 by Neuro Systems Inc. of Garland, Texas.

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SAUL LISS
59 Oxford Place • Glen Rock, New Jersey 07452
Office: (201) 652-1098 • Residence: (201) 652-6638

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

4. Standards

No known performance standards have been established by the Food and Drug Administration under section 514 of the Food Drug and Cosmetic Act.

5. Copies of the proposed label and instruction manual are included in Exhibits A and B. Promotional literature and advertisements have not yet been produced.

6. Statement of Substantial Equivalence

The MEDI Consultants, Inc. Model SBL202-B is substantially equivalent to the following listed device for the indications requested:

Exhibit C - Neuro Systems, Inc. Model - Neurotone 101

Exhibit D - Neuro Systems, Inc. Model - Relaxpak

Exhibit E - Chart Of Similarities between the LISS Cranial Stimulator and the products of Neuro Systems, Inc.

In our opinion, the information contained in Exhibits "B" through "E" verify the equivalence to devices currently being marketed.

MEDI Consultants, Inc. considers the existence of the 510 (k) notification and the intent to market the MEDI Model SBL202-B confidential commercial information and requests that the intent to market the product, the filing of this notice, and all information with regard to this submission be held in confidence.

If you have any questions or require additional informantion, please call me at (201) 652-1098.

Very truly yours,

Saul Liss

Saul Liss, President

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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EXHIBIT A

LISS Cranial Stimulator
[Zero DC]
Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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LISS Cranial Stimulator [Zero DC]
CAUTION:
To Be Used By Or On The Order Of An
M.D.,D.O.,or D.C. Licensed in the
State in which They Practice
Model No SBL202-B Serial No_____
MFD By: MEDI Consultants, Inc.
Glen Rock, N.J. 07452

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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EXHIBIT B

LISS Cranial Stimulator
[Zero DC]
Professional Instruction Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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MEDI Consultants, Inc.

MODEL No SBL202-B
LISS CRANIAL STIMULATOR
[Zero DC]

PROFESSIONAL INSTRUCTION MANUAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8018.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (240) 895-7... BEST COPY AVAILABLE

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1.0 INTRODUCTION

The LISS Cranial Stimulator [Zero DC] Model £ SBL202-B is a portable battery powered pulse generator used to reduce the symptoms of Depression, Anxiety, and Insomnia.

The LISS Cranial Stimulator [Zero DC] delivers an electrical stimulus which is conducted by the electrical cables to either water/wet sponges (supplied with the device) or self adhesive electrically conducting contacts to the tisue to which they are applied. Frequently, the LISS Cranial Stimulator [Zero DC] contacts can be applied from the skin over the spinal column at the base of the neck to various parts of the head and face. The contacts can also be placed on the head in a transcranial application, with one contact anterior to the top tip of the right ear and the other contact anterior to the top tip of the left ear.

2.0 Contraindications

Patients having cardiac pacemakers of the demand or sensing type should be aware that actions of the pacemakers may be inhibited or otherwise interfered with by this Cranial Electrotherapy Stimulator.

a. This device should not be used around the Carotid sinus.

b. Patients with known or suspected heart disease should not be stimulated.

c. Patients who react poorly to the idea of electrical stimulation of any kind should not use this device.

d. Patients whose skin is irritated around either electrode site should discontinue the use of this device.

e. This device must not be used until the physician has established the etiology of the Pain through a differential diagnosis. This device must be used only for the purpose for which a physician has prescribed. This device must only be used by the person for whom the prescription has been written.

3. Warnings

a. The safety of CES devices or use during pregnancy or delivery has not been establised.

b. CES devices should be used only under the continued supervision of a physician.

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explanation of the waveform: only significant difference from previous device.

c. CES is a symptomatic treatment and as such suppresses the symptoms of Depression, Anxiety, and Insomnia which would otherwise serve as a stimulus to see a Physician.

d. The user must keep the device out of reach of children.

e. Electronic monitoring equipment (such as ECG monitors, ECG alarms) may not operate properly when CES stimulation is in use.

4.0 Precautions-

a. Isolated cases of skin irritation may occur at the site of electrode placement following long term application.

b. Effectiveness is dependent upon patient selection and patient compliance.

5.0 Adverse Reactions-

a. There may be skin irritation with people who have sensitive skin. Proceed cautiously with short time exposures to prove skin viability.

b. Electrode burns can occur if the sponge deteriorates and contact is made between the skin and the metal contact behind the sponge.

6.0 Federal Labeling-

Federal Law (USA) restricts this device to sale by, or on the order of an M.D., D.O. or D.C., licensed in the state in which they practice.

7.0 THEORY OF OPERATION

a. The LISS Cranial Stimulator [Zero DC] is an electronic signal generator which has been shown to reduce the symptoms of Depression, Anxiety, and Insomnia.

The LISS Cranial Stimulator [Zero Dc] provides electrical connection from the signal generator through wire cables to the skin contacting method (either water/wet sponges [supplied with the device] or appropriate self adhesive electrically conductive contacts).

b. The electronic waveform of the LISS Cranial Stimulator [Zero DC] contains a 15,000 hz square wave carrier which is rectified, varying from zero to a maximum of 4 milliamperes. The first modulating signal of 15hz provides an "on" time of 50 milliseconds and an "off" time of 16.7 milliseconds. The second

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modulating signal of 500hz changes the "on" time series of 15,000hz carrier pulses (750 pulses in 50 milliseconds) into 25 smaller bursts of 15 pulses each of the 15,000hz carrier signal (375 pulses in the same 50milliseconds). (Waveform sketches are appended hereto.) The subject device is a bipolar version of a CES device, wherein the first major burst of energy (50 milliseconds is positive [above the zero axis], followed by a 16.7 millisecond "off" time), is then followed by a second major burst of energy (50 milliseconds is negative [below the axis], followed by a 16.7 millisecond "off" time. Thus, the consecutive positive burst and off time is followed by an equal and opposite negative burst and off time, balancing the direct current component to zero.

c. The pulse period for the basis carrier waveform of 15,000 hz is 66.7 microseconds (50 % duty Cycle).

d. The pulse period for the 1st Modulator of 15 hz is 66.7 milliseconds (75 % duty cycle).

e. The pulse period for the 2nd Modulator of 500 hz is 2 milliseconds (50 % duty cycle).

f. The output voltage is variable from zero to 40 volts and then voltage limited, first positive and then negative. Therefore, load impedances of up to 10,000 ohms will be able to have constant current up to 4 milli-amperes. However, beyond 10,000 ohms, the constant current is limited inversely with the load. (ie: A patient with a 10,000 ohm impedance will be able to receive a maximum of 2 milliamperes.)

g. A 9 volt alkaline battery is supplied. (non rechargeable)

8.0 INDICATIONS FOR USE OF THE SBL201-M

The Model SBL202-B device is an electronic signal generator which is indicated for the symptomatic relief of anxiety, depression, and insomnia.

9.0 DEVICE CONTROLS

The LISS Cranial Stimulator Model £SBL202-B has only one knob which encompasses both the on/off switch for turning the device on or off as well as the intensity control for adjusting the level of current which is delivered to the tissue.

a. There are two electrode lead receptacles. The color of the receptacles are the same (green) since the polarity is shifting automatically every major burst, there is no concern for polarity.

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b. There is a red LED indicator which flashes for the total time (ten [10] Minutes, set at the factory) when the device is turned on, no matter what the intensity.

c. There are four (4) amber LED indicators which flash according to the intensity:

INTENSITY (Peak ma)	£ OF Flashing INDICATORS
1	1
2	2
3	3
4	4

d. Low Battery is indicated by the non indication of the "on" lite when the on/off switch is turned into the "on" position.

10.0 SKIN PREPARATION

Good skin care is important in minimizing any skin irritations that may be encountered with the active use of the electrodes. Prepare the the skin before using the LISS Cranial Stimulator [Zero DC] by:

10.1 Thoroughly washing the skin sites where the electodes will be placed with a mild soap and water solution to remove nonconducting skin oils.

10.2 Rinsing the area with warm water and drying thoroughly.

11.0 APPLICATION OF THE DEVICE

11.1 Electrode Preparation

Place the Cellulose Sponge into the electrode receptacle in such a way that the edge of the receptacle fits into the slit depression in the side of the Sponge. This procedure should be done with the Sponge very wet and pliable. Connect the Electrode Receptacle to the Cable using the snap fastener connection. Insert the other end of the Cable via the plug into the Receptacle on the LISS Cranial stimulator [Zero DC].

11.2 Setting Device Controls

While holding the device in the hand with the Receptacles in the upper right side, rotate the intensity knob toward your body (Counterclockwise) using the right thumb. Be sure the device starts from the off position (Listen for and feel the click when the device is turned to the "off" position.).
To start the stimulation, rotate the intensity knob clockwise

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(Away from the body), listen for and feel the click when the device goes from the "off" position to the "on" position. Continue clockwise rotation, increasing the intensity until the patient feels a sensation (Itching, pins & needles, warmth or mosquito bite, or "light" flicker when it is used on the head). Then turn the intensity knob (Reducing) counterclockwise until the sensation disappears. If the patient feels the perception again, turn it down again. The patient does not have to feel the sensation in order for benefit to be derived. In fact, many people do not feel the sensation and yet, they get benefit, nonetheless.

11.3 Electrode Placement

11.3.1 Cranial Placement

For reducing the symptoms of Depression, Anxiety, or Sleeping Problems, place one contact on the head, anterior to the tip of the right ear and the other contact on the head, anterior to the tip of the left ear. Treatment time is ten (10) to twenty (20) minutes. Sponge contacts must be wet but not dripping.

11.3.2 Cranial Placement (Alternate 1)

For reducing the symptoms of Depression, Anxiety, or Sleeping Problems, place one contact on the Frontalis Midline and the other contact at the Occiput midline or bilateral contacts on the bilateral Mastoid Process Areas (piggyback contacts arranged on the instrument). Treatment is ten (10) to twenty (20) minutes.

12.0 Battery Replacement

In order to replace the battery, remove battery compartment cover by sliding the cover into the open position and detach the nine (9) volt battery from the battery clip and replace with another alkaline nine (9) volt battery. A rechargeable battery may be used. It must match the mechanical configuration and be a standard nine (9) volt battery.

13.0 Trouble Shooting

If the "on" LED lamp does not illuminate when the on switch is turned on, replace the nine (9) volt battery and turn the device on again. If it still does not illuminate, return the device for repair.

If the "on" LED lamp does go on but the intensity lamps do not illuminate, be sure the sponges are clean and wet; touch sponges together and raise the intensity; replace the wires in the output receptacles with a paper clip rebent to short circuit the receptacles. If the intensity lamps still do not illuminate, return the device for repair.

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14.0 Device Specification

PARAMETER	NOMINAL VALUE +/-10%
Output Amplitude into 1,000 Ohms	4.0 volts Pk.
Rate	15/500/15,000 hz
Pulse Width	33 microseconds
Maximum Charge per Pulse	.13 microcoulombs
On Time per Burst	50 milliseconds
Off Time per Burst	16.7milliseconds

Waveform = Assymmetrical bipolar square wave with double modulation. This waveform contains 25 bursts of 15 pulses each. Each pulse is 33.3 microsecond duration in a pulse period of 66.7 microseconds. (See appended sketch of the waveform.)

Power Source	9 volt Alkaline Battery
Contact dimension:	Approx.1.75"diam

Power Density:

Load Impedance Ohms	Power Density Watts/sq. in.
200	.0013
1,000	.0067
10,000	.0667

*Note: This device can not be connected to the power line

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15.0 LIMITED WARRANTY

MEDI Consultants, Inc. warrants each new LISS Cranial Stimulator [Zero DC] (exclusive of batteries) to be free from defects in materials and workmanship for a period of 18 months and accessories (not including disposables) for a period of 90 days following the delivery of the LISS Cranial Stimulator to the original purchaser. The obligation of MEDI Consultants, Inc. under this warranty is expressly limited solely and exclusively to the repair or replacement of the unit or any parts thereof, which to MEDI Consultants satisfaction, shall have become defective during the warranty period, and which shall have been returned to MEDI Consultants, Inc. within 30 days after the discovery of the defect by the original purchaser. This warranty does not extend to any liability for medical or dental expenses, or for any other direct, indirect or consequential damages caused by the failure, defect or malfunction of the LISS Cranial Stimulator, except as herein provided, whether such damage claim shall be based on contract, tort, breach of warranty, or otherwise.

This warranty shall not apply to any LISS Cranial Stimulator [Zero DC] which has been repaired, tampered with or altered by someone other than a duly authorized MEDI Consultant, Inc. representative, or which has been subjected to negligence, accident, mishandling or which has not been used in accordance with the enclosed instructions or for the stated purposes.

This warranty is expressly limited solely to the original purchaser (user) and does not extend to any transferee, assignee or subsequent purchaser or user of the LISS Cranial Stimulator.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY MADE OR WHICH MAY BE DEEMED TO HAVE BEEN MADE BY MEDI CONSULTANTS, INC. AND IS EXPRESSLY IN LIEU OF ANY AND ALL OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NO PERSON OR ENTITY HAS ANY AUTHORITY TO BIND MEDI CONSULTANTS, INC. TO ANY WARRANTY, GUARANTEE OR REPRESENTATION EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

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EXHIBIT C

Neurotone 101
(Preamendment Model)

By
Neuro Systems, Inc.

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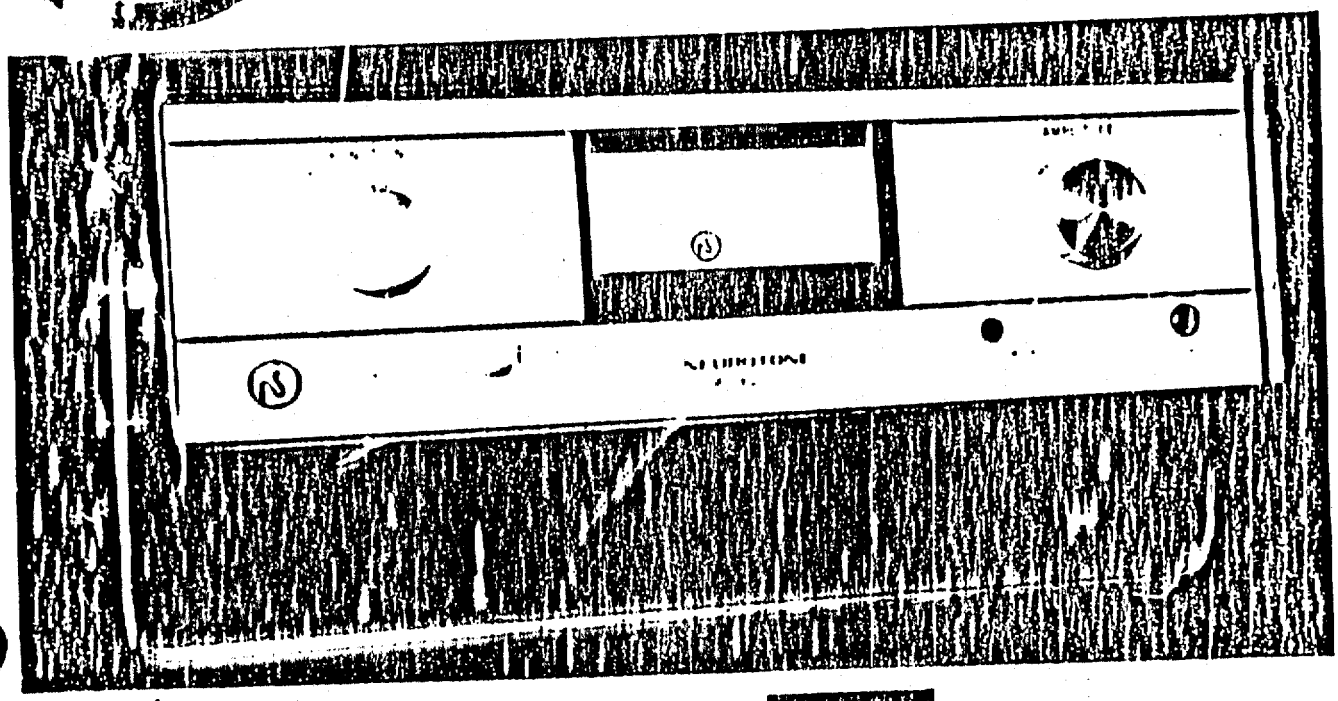
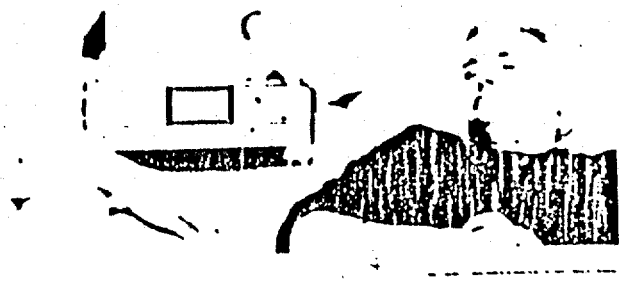
NEUROTONE 101

NEURO SYSTEMS INC 2709 NATIONAL GARLAND, TEXAS 75041 (214) 271 5118





CAUTION: Device restricted to sale by or on the order of a physician

Neurotone Model 101, complete with all accessories, is priced at only $695. F.O.B. destination Continental U.S. Texas residents add 5% Sales Tax

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NEUROTONE 101

TECHNICAL DATA

Description

The Neurotone 101 is a solid state cerebral electrotherapy (CET) device designed for use in a doctor's office, clinic or hospital. It weighs approximately 10 pounds and measures 15" x 4½" x 12", so it can be readily taken to point-of-treatment use. Its rechargeable battery and specially designed battery charger make it ideal for the ambulatory and home treatment in the preferred way. The CET treatment, which operates at 100 hertz, is applied through two headbands which plug into electrodes on the forehead and the mastoids. Or a bitemporal type electrode may be positioned behind each ear, below the pinnacle processes. The recommended treatment uses pulses of bipolar sine wave current. A function switch, however, gives the option of a unipolar square wave output. A single control knob turns the unit on and adjusts the amplitude, which is registered on a meter. All controls are on the front panel.

Output

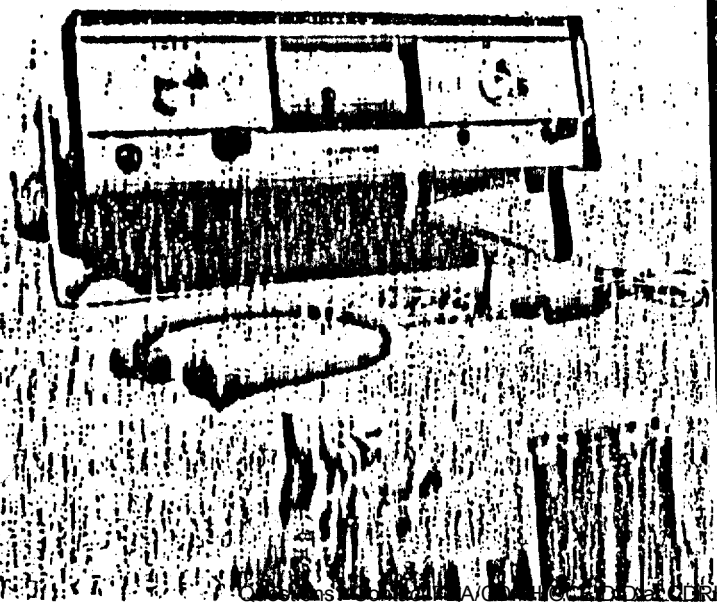
Wave shape	Sine wave.
Amplitude	Adjustable from 0 to 1.0 milliampere maximum.
Pulse duration	2 milliseconds (20% duty cycle).
Frequency	100 hertz.
Meter	Reads current level of CET in milliamperes.
Electrodes	One set of headbands with wiring assembly and disposable felt pads, and/or one set of bitemporal type.
Cables	Five to six feet in length, for easy lounge chair or bedside use.
Connectors	Output jack on the front panel for CET. Input jack for battery charger on bottom of case.

Battery operation

The CET operates from one 12 volt rechargable gel cell battery, Globe Union #GIC-1215 or equivalent, 1.5 ampere hours. Operating time is 10 to 15 hours at 1 milliampere CET output. Charging time is 12 to 16 hours, using ONLY Neuro Systems battery charger model BC-101.

Operating controls

The CET output has a combination on-off switch and variable potentiometer for adjustment of the amplitude from 0 to 1.0 milliamperes. An internal mercury switch permits operation only when the unit is in the down or horizontal position. This safety measure prevents operation of the unit when the charger is plugged into an AC outlet. A function switch permits selection of the recommended alternating (bipolar sine wave) output on setting "A" or a unipolar wave output on setting "B".



INDICATIONS

Cerebral electrotherapy treatment is generally indicated for [illegible] insomnia. Clinical indications show that symptomatic relief is frequently good in anxiety, tension, depression, and sleeping problems. While all patients do not respond therapeutically to electrical stimulation, several reports show that a majority for which it is indicated will gain. The duration of effectiveness will vary with individuals and the nature of the problem. While in some instances two to fifteen daily 30 minute treatments over a two to four week period will suffice, some doctors find that occasional "maintenance" treatments during periods of stress are desired.

PRECAUTIONS

Be sure electrodes are making proper contact and are placed according to directions detailed in the operating manual. Placing electrodes over eyes or applying them at full amplitude could cause an uncomfortable sting.

Some cerebral electrotherapy patients experience an increase in dreaming which may occasionally be alarming.

CET could inhibit the output of some cardiac pacemakers.

Some patients have reported experiencing a feeling of excitement or agitation rather than relaxation if a treatment is extended for a period beyond prescribed length or at abnormally high amplitude. Patients sensitive to normal dosage level of drugs, tranquilizers or sleep inducers, may require a shorter treatment time.

Occasionally, but rarely, a mild temporary headache is experienced. If this occurs several times in the same patient, the doctor should evaluate the benefit versus discomfort and consider whether treatments should be continued.

Refer to operating manual prior to use of the unit.

CONTRAINDICATIONS

Endogenous depressives sometimes become agitated or depressed. If there is a history of epilepsy, the possibility exists for triggering a seizure, although the treatment is not known to be harmful. It should not be used on patients having brain tumor, stroke or brain damage. It should not be used on paranoid schizophrenics.

CAUTION: The Neurotone is a prescription device. Federal law restricts it to sale by or on the order of a physician.

Questions? Contact FDA/CDRH/OC/DSMA/CDRH_DISTATUS@fda.hhs.gov

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EXHIBIT D

Relaxpak
(Present Model)

By

Neuro Systems, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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RelaxPak™ is a copyrighted trademark
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2735 National Place
Garland, Texas 75041

Caution: The RelaxPak is a prescription device. Federal law restricts it to sale by or on the order of a physician.

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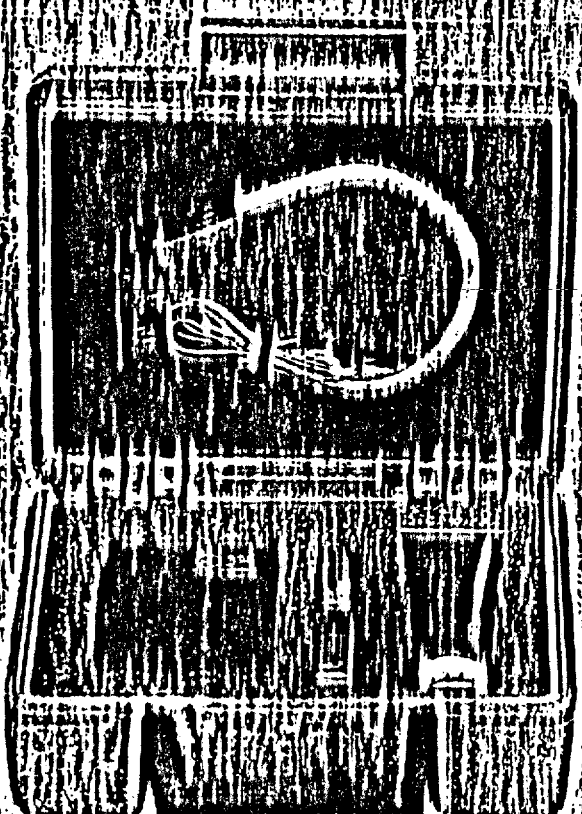

RelaxPak

For Stress Control

Produced by
Neuro Systems, Inc.

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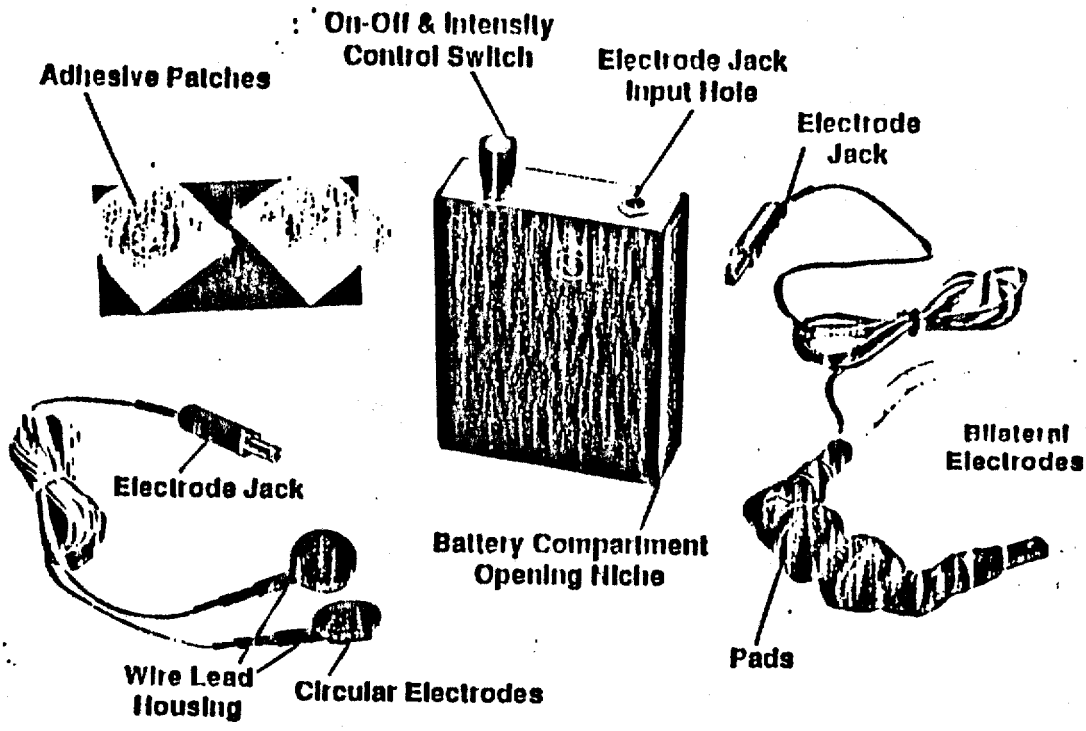

Introduction

This instruction booklet has been prepared to familiarize you with the RelaxPak.™ It also contains your warranty registration card and an accessories reorder form. Please read the entire booklet carefully, and send in your warranty registration card immediately.

In the course of your use of the RelaxPak, should questions arise that are not covered in the booklet, **CONTACT YOUR PHYSICIAN** or our customer service representative at the address on the inside cover of this booklet, or telephone (214) 271-5418, Garland, Texas.

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RelaxPak's highest current will not harm you in any way, it is not necessary to feel a current sensation in order for the beneficial effects of treatment to occur. In fact, it is best that you do not feel current at a level that is either unpleasant or distracting during treatment.

Remember, it is not necessary to feel the current on both sides of the head; most people don't. Ordinarily the side where the muscles are the most tense will respond with a sensation first. You can check this by turning your head to one side or the other while the current is on and feel the current sensation shift sides of the head. In this same way it is possible to balance the current sensation on both sides of the head, though, again, this is not necessary for treatment.

Note: Expected life of the bilateral electrodes is from three to six months.

To use With Circular Electrodes. First make sure the "off" switch is in the off position. Next, peel the backing paper from one of the adhesive pads, exposing its sticky surface. Place this adhesive surface over the circular electrode, facing against the electrode with the wire lead coming through the slit in the adhesive pad. Prepare the second lead similarly, then place the electrodes, one at a time, just behind the ear lobes in the indentation described above. Press adhesive tape securely all around the circular electrode so that it is held tightly against the skin surface. Finally, push the electrode jack

When to use

Use The RelaxPak As Your Physician Directs. Many physicians have patients use it for thirty or forty minutes a day, for anywhere from six to twenty successive days, depending on the type and amount of stress present. A general rule is to use it until you feel the stress has gone. Once the initial condition has subsided, physicians often encourage their patients to use the RelaxPak for thirty minutes per day, two to three times per week as a stress preventive measure. Other patients simply use it from time to time as they feel the need to relax. Still others use it for hours at a time without ill effects.

The RelaxPak is a prescription medical device, and should not be used by anyone except the person for whom it is prescribed.

How to use

To Use With Bilateral Electrodes. First make sure the "off" switch is in the off position. Moisten the pads with tap water and massage the water deep into the pads with your fingers. Squeeze out any excess water so that the pads are just moist, then place them just behind the ear lobes in the slight indentation where the jaw meets the rest of the head. Insert the electrode jack into the electrode jack input hole (see "features" page) and turn the "off" switch on. Increase the intensity of the current by rotating the "off" knob clockwise. Stop when the current gives you a pleasant tingle via one or both electrodes. You may leave it at this level or turn it up farther if you wish. You may also turn it back down to the point where the slight tingle just goes away. While the

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Some patients complain of headache (fewer than 3%) while using, or just following the use of the RelaxPak. If this occurs, try turning the current down or wear the unit for less time during each treatment session. If headaches persist, consult your physician.

While studies have not shown a reduction in reaction time during CES treatment, as with all treatments that are intended to induce relaxation, it is recommended that the unit not be used while driving or operating hazardous equipment.

How to change the batteries

Lift cover to battery compartment (see "features" page) by insert ing thumbnail in battery compartment opening niche and pulling outward. Lift out batteries by tilting RelaxPak slightly downward so batteries may slide out into your hand. They will be secured to a small two-inch connector board. Remove this from the batteries by gently but forcibly lifting it off the batteries with your fingers. Replace with new batteries by pushing them firmly into the connector fasteners on the connector board, then sliding them gently into the RelaxPak with wires to the knob side of the Pak. Close the door by placing it in position and pushing it into place.

How to use (continued)

into the electrode jack input hole and begin treatment by turning the "off" knob clockwise as described above in the use of the bilateral electrodes section.

Note: Should the adhesive not stick to your skin tightly it will be necessary to remove it, clean the skin with soap and water or an alcohol swab, then replace the circular electrodes after applying a new adhesive pad. Normally people feel more comfortable putting electrode jell on the circular electrodes prior to placing them against the skin since this sometimes allows the use of higher current levels with less sensation from the current on the skin. When jell is used it is important to avoid getting it on the adhesive surface of the adhesive pad which will not adhere to the skin with jell on it.

Indications for use

Cranial Electrotherapy Stimulation (CES) is a recognized treatment for insomnia, depression, or anxiety.

Caution

While there are no known negative side effects from use of this unit, you may experience slight twitching of muscles around the face, neck or eyelids when the current is set very high. This can be eliminated by turning the current down if you desire.

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Serial No. 11521

Limited Warranty

Neuro Systems, Inc., warrants for one year from date of purchase this RelaxPak™, against defects in workmanship and material. This warranty is limited to repair or replacement of any unit returned to our company by the user or his agent, which our inspection indicates is defective and which defect has occurred in the course of normal use as defined in the accompanying instructions. This warranty shall not extend to defects resulting from any other use or abuse of the unit.

Accessories, which appear on the accompanying parts resupply list carry a ninety (90) day warranty and will be repaired or replaced when the buyer returns them to our office within the 90 day warranty period. The purchaser, of this RelaxPak™ assumes liability for the consequence of its misuse by himself or others, including any use by persons whose treatment is not under the supervision or at the direction of a physician as required by Federal Law.

This warranty and the remedies given herein, is in lieu of all others either expressed or implied.

Date of Purchase_____

RelaxPak Accessories Reorder Form

Hints on proper care

The RelaxPak is relatively maintenance free in the course of normal use, other than the occasional need to change the batteries. Should the user wish to clean the case or other external parts, a soft cloth dipped in warm soapy water and wrung out prior to use should suffice to clean the outside of the case. Never dip the unit into water or liquid while cleaning since this may stop or significantly alter the working of the electronic parts inside. The bilateral electrodes may be cleaned in warm, soapy water and rinsed in clear water before placing them in circulating air to dry.

Never use harsh household detergents or special cleansers on either the case or the electrodes. Similarly, never use gasoline, turpentine, paint thinner or dry cleaning fluids when cleaning the unit or the electrodes. Should questions arise regarding the proper care of your RelaxPak, contact our consumer services representative at our home office address or call (214) 217-5418.

Specifications

The RelaxPak is powered by two, nine volt batteries and puts out an alternating current sine wave (~) 100 times each second, with .002 seconds rest between each sine wave burst. The maximum amount of current you can receive is .001 ampere, or about that required to run a flashlight...not enough to hurt you in any way, but enough to render very effective treatment for the conditions indicated.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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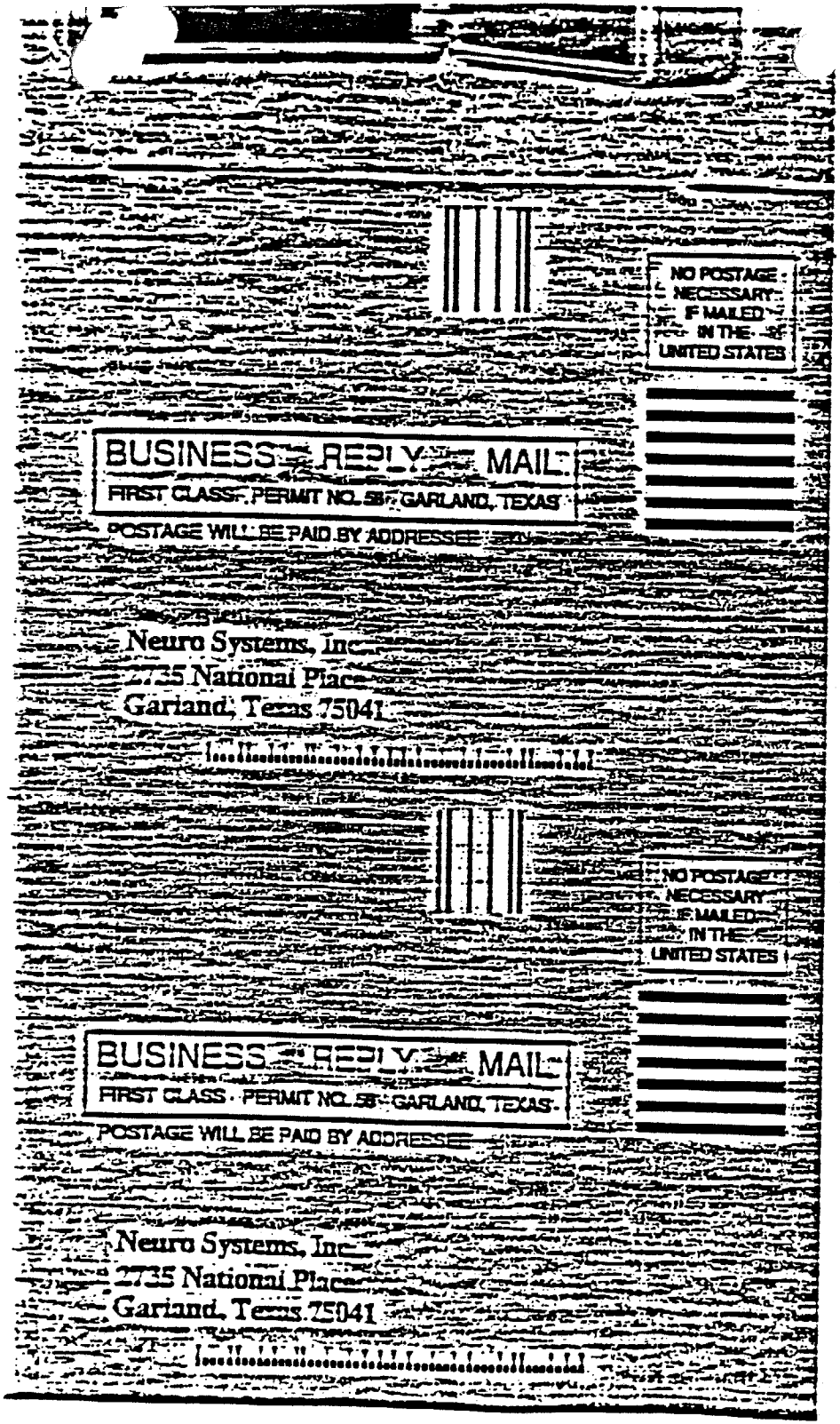

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BUSINESS REPLY MAIL
FIRST CLASS PERMIT NO. 58 GARLAND, TEXAS

POSTAGE WILL BE PAID BY ADDRESSEE

Neuro Systems, Inc.
2735 National Plac
Garland, Texas 75041

RelaxPak Accessories Reorder Form

Catalogue No.	No.	Amount
1038 Bilateral electrodes at $25.00 ea.		
1040 3/4" Rubber electrodes at $10.00pr.		
1043 36" Electrode wire leads at $8.00 ea.		
1103 Electrode jell #202 tube $1.50 ea.		
1092 Tape Disc (50/per pkg.) @ $5.00 per pkg.		

Name _____ Total _____

Address _____

Zip _____

Warranty Registration Card

Model: RelaxPak™

Serial No: 1152

Date of purchase _____

Prescribing Physician _____

Name _____ Phone No. _____

Address _____

Zip _____

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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EXHIBIT E

Chart of Similarities

* LISS Cranial Stimulator
  [Zero DC]
* Neurotone

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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CHART OF SIMILARITIES

Criteria	LISS Cranial Stimulator	Neurotone Model No. 101
Waveform	Square wave	Sine wave
Type	Bipolar Assymmetrical	Bipolar Assymmetrical
Burst Duty cycle	75% On time	20% On time
On Time Milliseconds	50	2
Frequency,hz	15,000-carrier modulated by 15, modulated by 500	1,000-carrier modulated by 100
Current, Milliamperes	0-4 peak	0-1.5
Treatment Time, Minutes	10 to 20	30
Indications	Symptomatic Relief of Anxiety, Depression, & Insomnia	Symptomatic Relief of Anxiety, Depression,& Sleeping Problems
Maximum Charge Per Pulse, Microcoulombs	0.133	0.750

Summary of output charact. as compared w/ Neurotone 101

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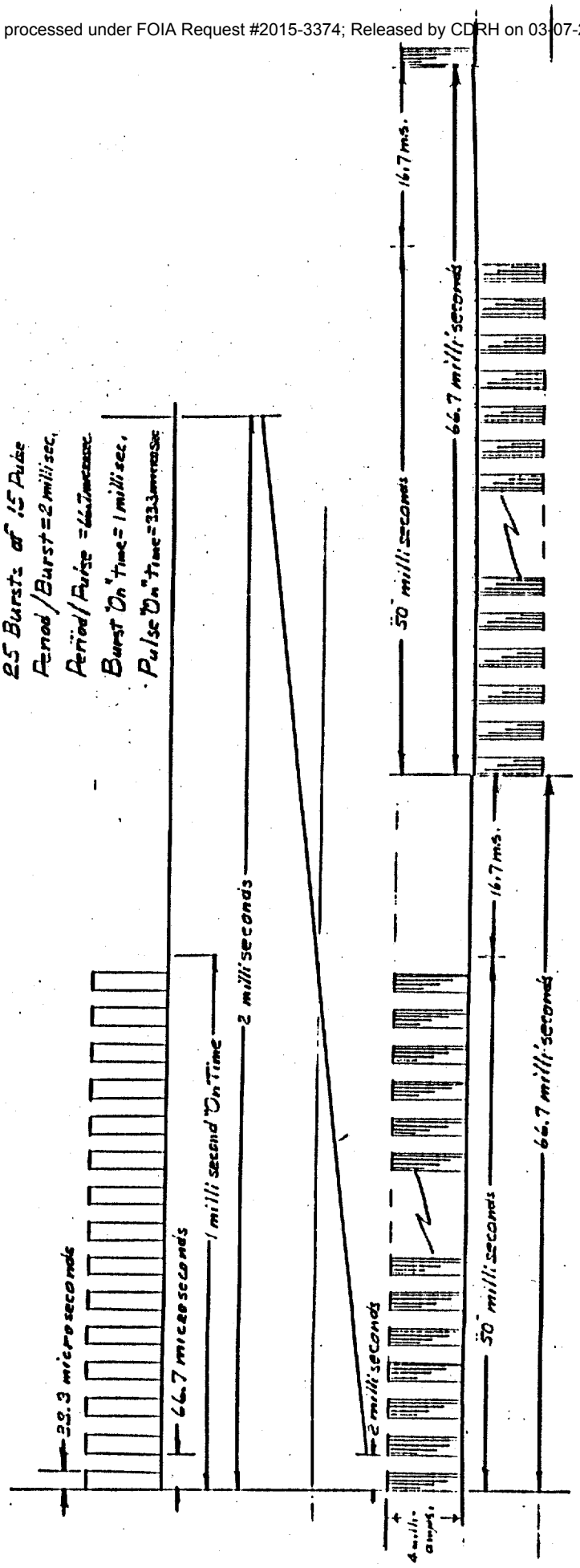
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

Waveform Analysis



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (301) 796-8144

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

OCT - 4 1990

Saul Liss
President
Medi Consultants, Inc.
59 Oxford Place
Glen Rock, New Jersey 07452

Re: K903654
Liss Cranial Stimulator Model SBL202-B
Regulatory Class: III
Dated: July 2, 1990
Received: July 6, 1990

Dear Mr. Liss:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

Your device is classified into class III (Premarket Approval). Class III devices will be required to undergo premarket approval at some time in the future. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

In our review of your submission, we noted that your device may violate the misbranding provisions of the law. The Food and Drug Administration's Neurological Devices Classification Panel has reported that the efficacy of cranial electrotherapy stimulation has not been established by well-controlled studies and that more investigation in this area is needed. Therefore, claims of effectiveness of your device for relief of anxiety, insomnia, and depression may cause your device to be misbranded. Before marketing your device, we strongly recommend that you consult with the Division of Compliance Operations concerning the labeling for your device to avoid a possible violations.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

David L. West, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices
and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request 2015-3374; Released by CDRH on 03-07-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OCT - 4 1990

Saul Liss
President
Medi Consultants, Inc.
59 Oxford Place
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FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ 430	MORRIS	9/14	2430		9/26	342		10/3/90
3		9/20	430		9/28/90	404		10/3/90
HFZ-430		9/25/90	323		10/3/90	464		10/4/90

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FDAINFO@fda.hhs.gov or call 301-796-8118

3

*U.S. GPO: 1989-619-669

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

David L. West, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices
and Radiological Health

cc: HFZ-401 (DMC)
HFZ-400 (ODE)
HFZ-402 (RChissler)
HFZ-430 (DANRD)
HFR-MA300

JMMorris:NE/510K #40
Draft:crd/9/13/90
Final:crd/9/13/90
Proofread:
Decspell:crd/9/13/90

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8...

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

Memorandum

Date . SEPTEMBER 25, 1990

From REVIEWER(S) - NAME(S) J. M. MORRIS

Subject 510(k) NOTIFICATION K903654

To THE RECORD

It is my recommendation that the subject 510(k) Notification: (b)(4)

✓ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

_____ (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

(b)(4)

The submitter requests under 21 CFR §807.95:

_____ No Confidentiality

✓ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

84 JXK Class III

Additional Product Code(s) w/Panel (optional):

CRANIAL ELECTRICAL STIMULATOR

REVIEW: 9/17/90 (BRANCH CHIEF) 9/25/90 (DATE)

FINAL REVIEW: 9/26/90 (DIVISION DIRECTOR) (DATE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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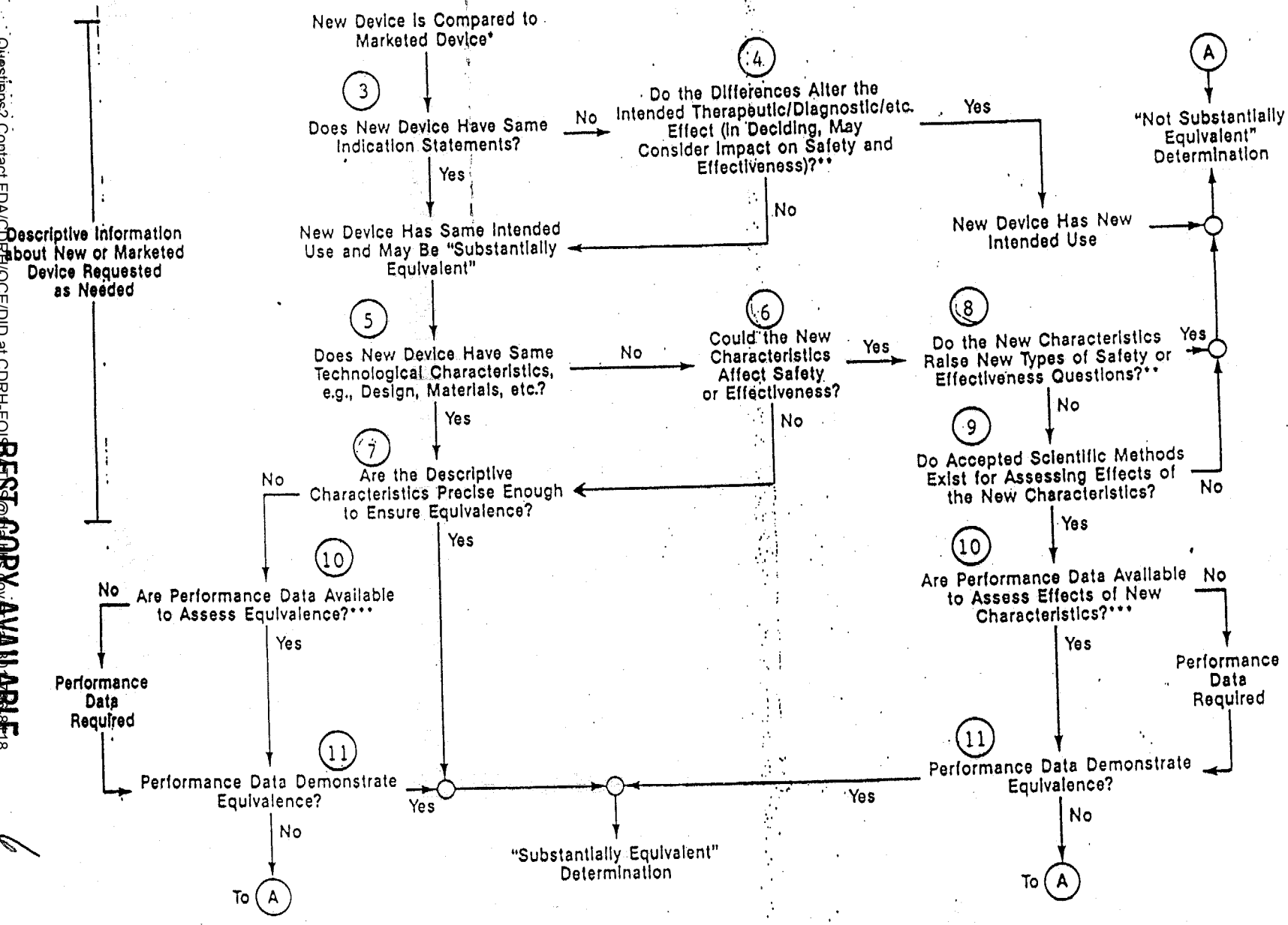
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) ... sions Compare New Devices to Marketed Devices. FDA Requests ... ormation If the Relationship Between Marketed and "Predicate" ... Add...

** This ... n Is Normally Based on Descriptive Information Alone, But ... Lim... ng Information Is Sometimes Required. ... In the 510(k), Other 510(k)'s, The Center's Classification Files, or the Literature.

*** Dat...

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@fda.hhs.gov 18.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

AUGUST 15, 1990

MEDI CONSULTANTS, INC.
ATTN: SAUL LISS
59 OXFORD PLACE
GLEN ROCK, NJ 07452

D.C. Number : K903654
Received : 07-06-90
90th Day : 10-04-90
Product : MEDI MODEL SBL202-B

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8113.

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Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

K 903654 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: J. Morris DIVISION/BRANCH: DANRD/NDBO

TRADE NAME: MEDI Model SBL202-B COMMON NAME: Liss Cranial Stimulator

PRODUCT TO WHICH COMPARED: Cranial Electrotherapy Stimulator, Neuro Systems, Inc.
(510(k) NUMBER IF KNOWN) Other 510Ks: K894515, K894097, K883812.

	YES	NO	
1. IS PRODUCT A DEVICE?	✓		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	✓		- IF NO STOP
3. SAME INDICATION STATEMENT?	✓		- IF YES GO TO 5
(4.) DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	✓		- IF YES GO TO 7
(6.) COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	✓		- IF NO GO TO 10 - IF YES STOP - SE
(8.) NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10. PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DAT
(11.) DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
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Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

510(k) Review

K 903654

Company: MEDI Consultants, Inc.

Device Proprietary Name: MEDI Model SBL202-B

1. Is this device life-supporting or life-sustaining? no

2. Is this an implanted device (short-term or long-term)? no

3. If device incorporates a microprocessor, does the firm certify that testing has shown that shows all system requirements are fulfilled and that software changes will require retesting before release? Estimated level of concern is: (Major, Moderate, Minor).

no

4. Subject device can be compared to (prior devices): Neurotone 101, NeuroSystems, Inc. (device name, manufacturer)
MEDI Model SBL201-M, MEDI Consultants, Inc. (K894515)
NTI-1000, Neurotek, Inc. (K894097)
Health Pax HP-1, Health Directions, Inc (K883812)

5. Submission provides: comparative specifications? yes

bench test or in vitro data? *yes animal test data? no

clinical data? no ref. to industry stds? no

6. SUMMARY (device characteristics; differences between device and preenactment (predicate) devices; new intended use; new technology and new kinds of safety issues):

* see attached summary sheet
(bench test data refers to the waveform analysis)

7. RECOMMENDATION:

I believe that this device is equivalent to: 84 JXK
(panel & product codes)

Classification should be based on: 882.5800
(CFR Section # and device name)

Cranial Electrotherapy Stimulator presently class: III

Janice M. Morris 9/14/90
(signed, date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

SAMPLE WAVEFORM ANALYSIS FOR LISS CES MODEL SBL202-B (K903654)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

SAMPLE WAVEFORM ANALYSIS FOR LISS CES MODEL SBL201-M (K894515)
(PREVIOUS 510K SUBMISSION)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (301) 796-9718

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

MEDI CONSULTANTS, INC.

K903654

July 2, 1990

Office of Device Evaluation
510 (K) Document Mail Center (HFZ-401)
Center for Devices & Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

RECEIVED
6 Jul 90 07 8
FDA/CDRH/ODE/DMC

Re: Notice of 510 (k) Premarket Notification (LISS Cranial Stimulator [Zero DC])

Gentlemen:

In accordance with Section 510 (k) of the Federal Food, Drug and Cosmetic Act, and in conformance with Title 21 of Federal Regulations Part 807, this premarket notification is being submitted 90 days prior to the date on which MEDI Consultants, Inc. proposes to introduce into interstate commerce a Cranial Electrotherapy Device to be known as the LISS Cranial Stimulator Model [Zero DC] SBL202-B.

The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name: Cranial Electrotherapy Stimulator

   Common/Usual Name: LISS Cranial Stimulator [Zero DC]

   Trade/Proprietary Name: MEDI Model SBL202-B

2. Establishment Registration Number

MEDI Consultants, Inc. has submitted Form 2891 (Initial Registration of Medical Device Establishment) for its manufacturing facility located at 59 Oxford Place, in Glen Rock, New Jersey 07452). The facility is now located at 175 Rock Road in Glen Rock, New Jersey 07452-1724.

3. Classification

The Cranial Electrotherapy Stimulator is equivalent in performance to equipment which was in commercial distribution, preamendment (May 28,1976). Please note appendices describing preamendment device, Neurotone 101 by Neuro Systems Inc. of Garland, Texas.

BEST COPY AVAILABLE

SAUL LISS
59 Oxford Place • Glen Rock, New Jersey 07452
Office: (201) 652-1098 • Residence: (201) 652-6638

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

4. Standards

No known performance standards have been established by the Food and Drug Administration under section 514 of the Food Drug and Cosmetic Act.

5. Copies of the proposed label and instruction manual are included in Exhibits A and B. Promotional literature and advertisements have not yet been produced.

6. Statement of Substantial Equivalence

The MEDI Consultants, Inc. Model SBL202-B is substantially equivalent to the following listed device for the indications requested:

Exhibit C - Neuro Systems, Inc. Model - Neurotone 101

Exhibit D - Neuro Systems, Inc. Model - Relaxpak

Exhibit E - Chart Of Similarities between the LISS Cranial Stimulator and the products of Neuro Systems, Inc.

In our opinion, the information contained in Exhibits "B" through "E" verify the equivalence to devices currently being marketed.

MEDI Consultants, Inc. considers the existence of the 510 (k) notification and the intent to market the MEDI Model SBL202-B confidential commercial information and requests that the intent to market the product, the filing of this notice, and all information with regard to this submission be held in confidence.

If you have any questions or require additional informantion, please call me at (201) 652-1098.

Very truly yours,

Saul Liss

Saul Liss, President

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

EXHIBIT A

LISS Cranial Stimulator
[Zero DC]
Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

LISS Cranial Stimulator [Zero DC]
CAUTION:
To Be Used By Or On The Order Of An
M.D.,D.O.,or D.C. Licensed in the
State in which They Practice
Model No SBL202-B Serial No_____
MFD By: MEDI Consultants, Inc.
Glen Rock, N.J. 07452

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

EXHIBIT B

LISS Cranial Stimulator
[Zero DC]
Professional Instruction Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

BEST COPY AVAILABLE

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

MEDI Consultants, Inc.

MODEL No SBL202-B
LISS CRANIAL STIMULATOR
[Zero DC]

PROFESSIONAL INSTRUCTION MANUAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8018.

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Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or (240) 895-7... BEST COPY AVAILABLE

Records processed under FOIA Request #2015-3374; Released by CDRH on 03-07-2016.

1.0 INTRODUCTION

The LISS Cranial Stimulator [Zero DC] Model £ SBL202-B is a portable battery powered pulse generator used to reduce the symptoms of Depression, Anxiety, and Insomnia.

The LISS Cranial Stimulator [Zero DC] delivers an electrical stimulus which is conducted by the electrical cables to either water/wet sponges (supplied with the device) or self adhesive electrically conducting contacts to the tisue to which they are applied. Frequently, the LISS Cranial Stimulator [Zero DC] contacts can be applied from the skin over the spinal column at the base of the neck to various parts of the head and face. The contacts can also be placed on the head in a transcranial application, with one contact anterior to the top tip of the right ear and the other contact anterior to the top tip of the left ear.

2.0 Contraindications

Patients having cardiac pacemakers of the demand or sensing type should be aware that actions of the pacemakers may be inhibited or otherwise interfered with by this Cranial Electrotherapy Stimulator.

a. This device should not be used around the Carotid sinus.

b. Patients with known or suspected heart disease should not be stimulated.

c. Patients who react poorly to the idea of electrical stimulation of any kind should not use this device.

d. Patients whose skin is irritated around either electrode site should discontinue the use of this device.

e. This device must not be used until the physician has established the etiology of the Pain through a differential diagnosis. This device must be used only for the purpose for which a physician has prescribed. This device must only be used by the person for whom the prescription has been written.

3. Warnings

a. The safety of CES devices or use during pregnancy or delivery has not been establised.

b. CES devices should be used only under the continued supervision of a physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
BEST COPY AVAILABLE

Records processed under (b)(4) on 03-07-2016.

c. CES is a symptomatic treatment and as such suppresses the symptoms of Depression, Anxiety, and Insomnia which would otherwise serve as a stimulus to see a Physician.

d. The user must keep the device out of reach of children.

e. Electronic monitoring equipment (such as ECG monitors, ECG alarms) may not operate properly when CES stimulation is in use.

4.0 Precautions-

a. Isolated cases of skin irritation may occur at the site of electrode placement following long term application.

b. Effectiveness is dependent upon patient selection and patient compliance.

5.0 Adverse Reactions-

a. There may be skin irritation with people who have sensitive skin. Proceed cautiously with short time exposures to prove skin viability.

b. Electrode burns can occur if the sponge deteriorates and contact is made between the skin and the metal contact behind the sponge.

6.0 Federal Labeling-

Federal Law (USA) restricts this device to sale by, or on the order of an M.D., D.O. or D.C., licensed in the state in which they practice.

7.0 THEORY OF OPERATION

a. The LISS Cranial Stimulator [Zero DC] is an electronic signal generator which has been shown to reduce the symptoms of Depression, Anxiety, and Insomnia.

The LISS Cranial Stimulator [Zero Dc] provides electrical connection from the signal generator through wire cables to the skin contacting method (either water/wet sponges [supplied with the device] or appropriate self adhesive electrically conductive contacts).

b. The electronic waveform of the LISS Cranial Stimulator [Zero DC] contains a 15,000 hz square wave carrier which is rectified, varying from zero to a maximum of 4 milliamperes. The first modulating signal of 15hz provides an "on" time of 50 milliseconds and an "off" time of 16.7 milliseconds. The second

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modulating signal of 500hz changes the "on" time series of 15,000hz carrier pulses (750 pulses in 50 milliseconds) into 25 smaller bursts of 15 pulses each of the 15,000hz carrier signal (375 pulses in the same 50milliseconds). (Waveform sketches are appended hereto.) The subject device is a bipolar version of a CES device, wherein the first major burst of energy (50 milliseconds is positive [above the zero axis], followed by a 16.7 millisecond "off" time), is then followed by a second major burst of energy (50 milliseconds is negative [below the axis], followed by a 16.7 millisecond "off" time. Thus, the consecutive positive burst and off time is followed by an equal and opposite negative burst and off time, balancing the direct current component to zero.

c. The pulse period for the basis carrier waveform of 15,000 hz is 66.7 microseconds (50 % duty Cycle).

d. The pulse period for the 1st Modulator of 15 hz is 66.7 milliseconds (75 % duty cycle).

e. The pulse period for the 2nd Modulator of 500 hz is 2 milliseconds (50 % duty cycle).

f. The output voltage is variable from zero to 40 volts and then voltage limited, first positive and then negative. Therefore, load impedances of up to 10,000 ohms will be able to have constant current up to 4 milli-amperes. However, beyond 10,000 ohms, the constant current is limited inversely with the load. (ie: A patient with a 10,000 ohm impedance will be able to receive a maximum of 2 milliamperes.)

g. A 9 volt alkaline battery is supplied. (non rechargeable)

8.0 INDICATIONS FOR USE OF THE SBL201-M

The Model SBL202-B device is an electronic signal generator which is indicated for the symptomatic relief of anxiety, depression, and insomnia.

9.0 DEVICE CONTROLS

The LISS Cranial Stimulator Model £SBL202-B has only one knob which encompasses both the on/off switch for turning the device on or off as well as the intensity control for adjusting the level of current which is delivered to the tissue.

a. There are two electrode lead receptacles. The color of the receptacles are the same (green) since the polarity is shifting automatically every major burst, there is no concern for polarity.

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b. There is a red LED indicator which flashes for the total time (ten [10] Minutes, set at the factory) when the device is turned on, no matter what the intensity.

c. There are four (4) amber LED indicators which flash according to the intensity:

INTENSITY (Peak ma)	£ OF Flashing INDICATORS
1	1
2	2
3	3
4	4

d. Low Battery is indicated by the non indication of the "on" lite when the on/off switch is turned into the "on" position.

10.0 SKIN PREPARATION

Good skin care is important in minimizing any skin irritations that may be encountered with the active use of the electrodes. Prepare the the skin before using the LISS Cranial Stimulator [Zero DC] by:

10.1 Thoroughly washing the skin sites where the electodes will be placed with a mild soap and water solution to remove nonconducting skin oils.

10.2 Rinsing the area with warm water and drying thoroughly.

11.0 APPLICATION OF THE DEVICE

11.1 Electrode Preparation

Place the Cellulose Sponge into the electrode receptacle in such a way that the edge of the receptacle fits into the slit depression in the side of the Sponge. This procedure should be done with the Sponge very wet and pliable. Connect the Electrode Receptacle to the Cable using the snap fastener connection. Insert the other end of the Cable via the plug into the Receptacle on the LISS Cranial stimulator [Zero DC].

11.2 Setting Device Controls

While holding the device in the hand with the Receptacles in the upper right side, rotate the intensity knob toward your body (Counterclockwise) using the right thumb. Be sure the device starts from the off position (Listen for and feel the click when the device is turned to the "off" position.).
To start the stimulation, rotate the intensity knob clockwise

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(Away from the body), listen for and feel the click when the device goes from the "off" position to the "on" position. Continue clockwise rotation, increasing the intensity until the patient feels a sensation (Itching, pins & needles, warmth or mosquito bite, or "light" flicker when it is used on the head). Then turn the intensity knob (Reducing) counterclockwise until the sensation disappears. If the patient feels the perception again, turn it down again. The patient does not have to feel the sensation in order for benefit to be derived. In fact, many people do not feel the sensation and yet, they get benefit, nonetheless.

11.3 Electrode Placement

11.3.1 Cranial Placement

For reducing the symptoms of Depression, Anxiety, or Sleeping Problems, place one contact on the head, anterior to the tip of the right ear and the other contact on the head, anterior to the tip of the left ear. Treatment time is ten (10) to twenty (20) minutes. Sponge contacts must be wet but not dripping.

11.3.2 Cranial Placement (Alternate 1)

For reducing the symptoms of Depression, Anxiety, or Sleeping Problems, place one contact on the Frontalis Midline and the other contact at the Occiput midline or bilateral contacts on the bilateral Mastoid Process Areas (piggyback contacts arranged on the instrument). Treatment is ten (10) to twenty (20) minutes.

12.0 Battery Replacement

In order to replace the battery, remove battery compartment cover by sliding the cover into the open position and detach the nine (9) volt battery from the battery clip and replace with another alkaline nine (9) volt battery. A rechargeable battery may be used. It must match the mechanical configuration and be a standard nine (9) volt battery.

13.0 Trouble Shooting

If the "on" LED lamp does not illuminate when the on switch is turned on, replace the nine (9) volt battery and turn the device on again. If it still does not illuminate, return the device for repair.

If the "on" LED lamp does go on but the intensity lamps do not illuminate, be sure the sponges are clean and wet; touch sponges together and raise the intensity; replace the wires in the output receptacles with a paper clip rebent to short circuit the receptacles. If the intensity lamps still do not illuminate, return the device for repair.

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15.0 LIMITED WARRANTY

MEDI Consultants, Inc. warrants each new LISS Cranial Stimulator [Zero DC] (exclusive of batteries) to be free from defects in materials and workmanship for a period of 18 months and accessories (not including disposables) for a period of 90 days following the delivery of the LISS Cranial Stimulator to the original purchaser. The obligation of MEDI Consultants, Inc. under this warranty is expressly limited solely and exclusively to the repair or replacement of the unit or any parts thereof, which to MEDI Consultants satisfaction, shall have become defective during the warranty period, and which shall have been returned to MEDI Consultants, Inc. within 30 days after the discovery of the defect by the original purchaser. This warranty does not extend to any liability for medical or dental expenses, or for any other direct, indirect or consequential damages caused by the failure, defect or malfunction of the LISS Cranial Stimulator, except as herein provided, whether such damage claim shall be based on contract, tort, breach of warranty, or otherwise.

This warranty shall not apply to any LISS Cranial Stimulator [Zero DC] which has been repaired, tampered with or altered by someone other than a duly authorized MEDI Consultant, Inc. representative, or which has been subjected to negligence, accident, mishandling or which has not been used in accordance with the enclosed instructions or for the stated purposes.

This warranty is expressly limited solely to the original purchaser (user) and does not extend to any transferee, assignee or subsequent purchaser or user of the LISS Cranial Stimulator.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY MADE OR WHICH MAY BE DEEMED TO HAVE BEEN MADE BY MEDI CONSULTANTS, INC. AND IS EXPRESSLY IN LIEU OF ANY AND ALL OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NO PERSON OR ENTITY HAS ANY AUTHORITY TO BIND MEDI CONSULTANTS, INC. TO ANY WARRANTY, GUARANTEE OR REPRESENTATION EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

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EXHIBIT C

Neurotone 101
(Preamendment Model)

By
Neuro Systems, Inc.

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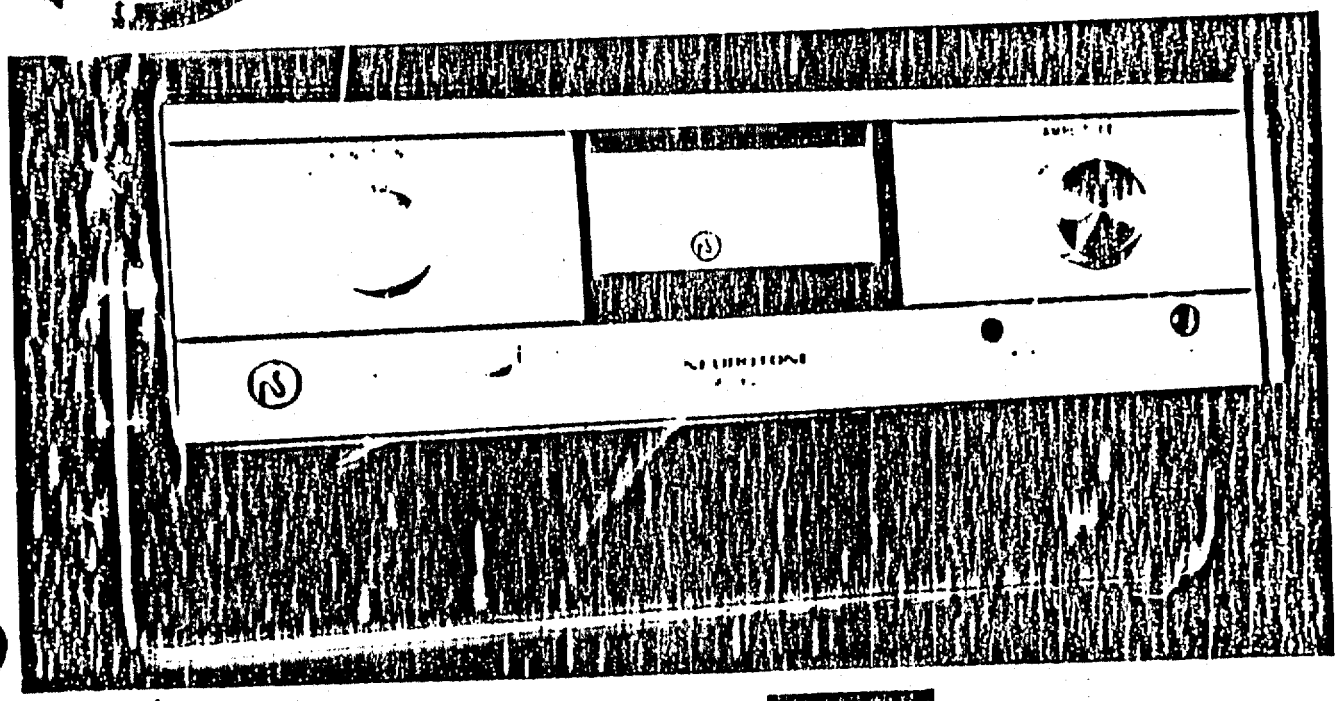
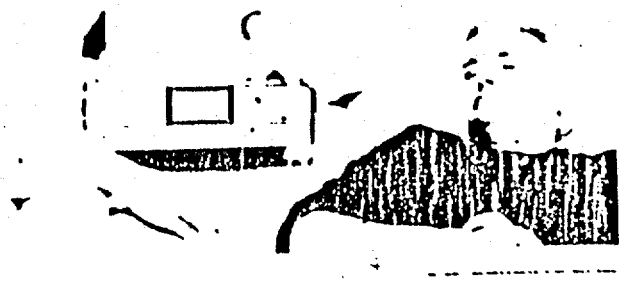
NEUROTONE 101

NEURO SYSTEMS INC 2709 NATIONAL GARLAND, TEXAS 75041 (214) 271 5118





CAUTION: Device restricted to sale by or on the order of a physician

Neurotone Model 101, complete with all accessories, is priced at only $695. F.O.B. destination Continental U.S. Texas residents add 5% Sales Tax

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NEUROTONE 101

TECHNICAL DATA

Description

The Neurotone 101 is a solid state cerebral electrotherapy (CET) device designed for use in a doctor's office, clinic or hospital. It weighs approximately 10 pounds and measures 15" x 4½" x 12", so it can be readily taken to point-of-treatment use. Its rechargeable battery and specially designed battery charger make it ideal for the ambulatory and home treatment in the preferred way. The CET treatment, which operates at 100 hertz, is applied through two headbands which plug into electrodes on the forehead and the mastoids. Or a bitemporal type electrode may be positioned behind each ear, below the pinnacle processes. The recommended treatment uses pulses of bipolar sine wave current. A function switch, however, gives the option of a unipolar square wave output. A single control knob turns the unit on and adjusts the amplitude, which is registered on a meter. All controls are on the front panel.

Output

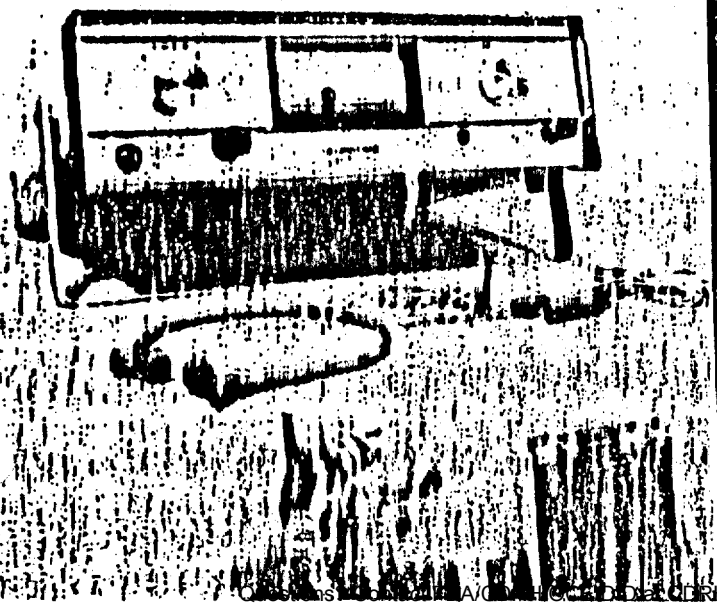
Wave shape	Sine wave.
Amplitude	Adjustable from 0 to 1.0 milliampere maximum.
Pulse duration	2 milliseconds (20% duty cycle).
Frequency	100 hertz.
Meter	Reads current level of CET in milliamperes.
Electrodes	One set of headbands with wiring assembly and disposable felt pads, and/or one set of bitemporal type.
Cables	Five to six feet in length, for easy lounge chair or bedside use.
Connectors	Output jack on the front panel for CET. Input jack for battery charger on bottom of case.

Battery operation

The CET operates from one 12 volt rechargable gel cell battery, Globe Union #GIC-1215 or equivalent, 1.5 ampere hours. Operating time is 10 to 15 hours at 1 milliampere CET output. Charging time is 12 to 16 hours, using ONLY Neuro Systems battery charger model BC-101.

Operating controls

The CET output has a combination on-off switch and variable potentiometer for adjustment of the amplitude from 0 to 1.0 milliamperes. An internal mercury switch permits operation only when the unit is in the down or horizontal position. This safety measure prevents operation of the unit when the charger is plugged into an AC outlet. A function switch permits selection of the recommended alternating (bipolar sine wave) output on setting "A" or a unipolar wave output on setting "B".



INDICATIONS

Cerebral electrotherapy treatment is generally indicated for [illegible] insomnia. Clinical indications show that symptomatic relief is frequently good in anxiety, tension, depression, and sleeping problems. While all patients do not respond therapeutically to electrical stimulation, several reports show that a majority for which it is indicated will gain. The duration of effectiveness will vary with individuals and the nature of the problem. While in some instances two to fifteen daily 30 minute treatments over a two to four week period will suffice, some doctors find that occasional "maintenance" treatments during periods of stress are desired.

PRECAUTIONS

Be sure electrodes are making proper contact and are placed according to directions detailed in the operating manual. Placing electrodes over eyes or applying them at full amplitude could cause an uncomfortable sting.

Some cerebral electrotherapy patients experience an increase in dreaming which may occasionally be alarming.

CET could inhibit the output of some cardiac pacemakers.

Some patients have reported experiencing a feeling of excitement or agitation rather than relaxation if a treatment is extended for a period beyond prescribed length or at abnormally high amplitude. Patients sensitive to normal dosage level of drugs, tranquilizers or sleep inducers, may require a shorter treatment time.

Occasionally, but rarely, a mild temporary headache is experienced. If this occurs several times in the same patient, the doctor should evaluate the benefit versus discomfort and consider whether treatments should be continued.

Refer to operating manual prior to use of the unit.

CONTRAINDICATIONS

Endogenous depressives sometimes become agitated or depressed. If there is a history of epilepsy, the possibility exists for triggering a seizure, although the treatment is not known to be harmful. It should not be used on patients having brain tumor, stroke or brain damage. It should not be used on paranoid schizophrenics.

CAUTION: The Neurotone is a prescription device. Federal law restricts it to sale by or on the order of a physician.

Questions? Contact FDA/CDRH/OC/DSMA/CDRH_DISTATUS@fda.hhs.gov

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EXHIBIT D

Relaxpak
(Present Model)

By

Neuro Systems, Inc.

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RelaxPak™ is a copyrighted trademark
1981 by Neuro Systems, Inc.
2735 National Place
Garland, Texas 7504[illegible]

Caution: The RelaxPak is a prescription device. Federal law restricts it to sale by or on the order of a physician.

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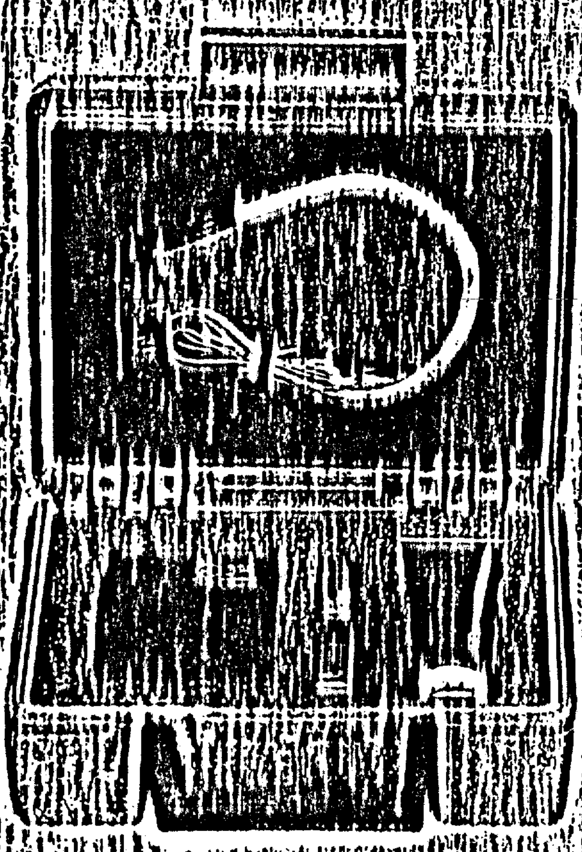

RelaxPak
For Stress Control

Produced by
Neuro Systems, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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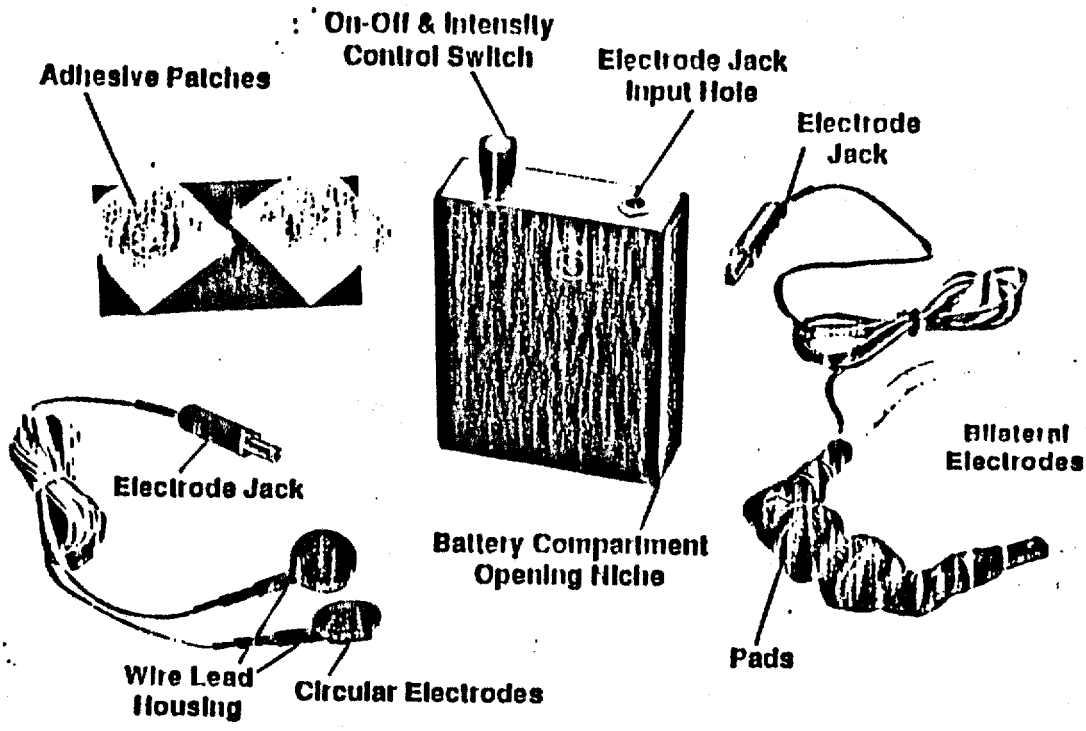

Introduction

This instruction booklet has been prepared to familiarize you with the RelaxPak.™ It also contains your warranty registration card and an accessories reorder form. Please read the entire booklet carefully, and send in your warranty registration card immediately.

In the course of your use of the RelaxPak, should questions arise that are not covered in the booklet, **CONTACT YOUR PHYSICIAN** or our customer service representative at the address on the inside cover of this booklet, or telephone (214) 271-5418, Garland, Texas.

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When to Use	3
How to Use	3,4,5
Indications for use	5
Caution	5,6
How to Change the Batteries	6
Hints on Proper Care	7
Specifications	7
Warranty	8

RelaxPak™ is a registered trademark of Neuro Systems, Inc., Garland, Texas.

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RelaxPak's highest current will not harm you in any way, it is not necessary to feel a current sensation in order for the beneficial effects of treatment to occur. In fact, it is best that you do not feel current at a level that is either unpleasant or distracting during treatment.

Remember, it is not necessary to feel the current on both sides of the head; most people don't. Ordinarily the side where the muscles are the most tense will respond with a sensation first. You can check this by turning your head to one side or the other while the current is on and feel the current sensation shift sides of the head. In this same way it is possible to balance the current sensation on both sides of the head, though, again, this is not necessary for treatment.

Note: Expected life of the bilateral electrodes is from three to six months.

To use With Circular Electrodes. First make sure the "off" switch is in the off position. Next, peel the backing paper from one of the adhesive pads, exposing its sticky surface. Place this adhesive surface over the circular electrode, facing against the electrode with the wire lead coming through the slit in the adhesive pad. Prepare the second lead similarly, then place the electrodes, one at a time, just behind the ear lobes in the indentation described above. Press adhesive tape securely all around the circular electrode so that it is held tightly against the skin surface. Finally, push the electrode jack

When to use

Use The RelaxPak As Your Physician Directs. Many physicians have patients use it for thirty or forty minutes a day, for anywhere from six to twenty successive days, depending on the type and amount of stress present. A general rule is to use it until you feel the stress has gone. Once the initial condition has subsided, physicians often encourage their patients to use the RelaxPak for thirty minutes per day, two to three times per week as a stress preventive measure. Other patients simply use it from time to time as they feel the need to relax. Still others use it for hours at a time without ill effects.

The RelaxPak is a prescription medical device, and should not be used by anyone except the person for whom it is prescribed.

How to use

To Use With Bilateral Electrodes. First make sure the "off" switch is in the off position. Moisten the pads with tap water and massage the water deep into the pads with your fingers. Squeeze out any excess water so that the pads are just moist, then place them just behind the ear lobes in the slight indentation where the jaw meets the rest of the head. Insert the electrode jack into the electrode jack input hole (see "features" page) and turn the "off" switch on. Increase the intensity of the current by rotating the "off" knob clockwise. Stop when the current gives you a pleasant tingle via one or both electrodes. You may leave it at this level or turn it up farther if you wish. You may also turn it back down to the point where the slight tingle just goes away. While the

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Some patients complain of headache (fewer than 3%) while using, or just following the use of the RelaxPak. If this occurs, try turning the current down or wear the unit for less time during each treatment session. If headaches persist, consult your physician.

While studies have not shown a reduction in reaction time during CES treatment, as with all treatments that are intended to induce relaxation, it is recommended that the unit not be used while driving or operating hazardous equipment.

How to change the batteries

Lift cover to battery compartment (see "features" page) by insert ing thumbnail in battery compartment opening niche and pulling outward. Lift out batteries by tilting RelaxPak slightly downward so batteries may slide out into your hand. They will be secured to a small two-inch connector board. Remove this from the batteries by gently but forcibly lifting it off the batteries with your fingers. Replace with new batteries by pushing them firmly into the connector fasteners on the connector board, then sliding them gently into the RelaxPak with wires to the knob side of the Pak. Close the door by placing it in position and pushing it into place.

How to use (continued)

into the electrode jack input hole and begin treatment by turning the "off" knob clockwise as described above in the use of the bilateral electrodes section.

Note: Should the adhesive not stick to your skin tightly it will be necessary to remove it, clean the skin with soap and water or an alcohol swab, then replace the circular electrodes after applying a new adhesive pad. Normally people feel more comfortable putting electrode jell on the circular electrodes prior to placing them against the skin since this sometimes allows the use of higher current levels with less sensation from the current on the skin. When jell is used it is important to avoid getting it on the adhesive surface of the adhesive pad which will not adhere to the skin with jell on it.

Indications for use

Cranial Electrotherapy Stimulation (CES) is a recognized treatment for insomnia, depression, or anxiety.

Caution

While there are no known negative side effects from use of this unit, you may experience slight twitching of muscles around the face, neck or eyelids when the current is set very high. This can be eliminated by turning the current down if you desire.

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Serial No. 11521

Limited Warranty

Neuro Systems, Inc., warrants for one year from date of purchase this RelaxPak™, against defects in workmanship and material. This warranty is limited to repair or replacement of any unit returned to our company by the user or his agent, which our inspection indicates is defective and which defect has occurred in the course of normal use as defined in the accompanying instructions. This warranty shall not extend to defects resulting from any other use or abuse of the unit.

Accessories, which appear on the accompanying parts resupply list carry a ninety (90) day warranty and will be repaired or replaced when the buyer returns them to our office within the 90 day warranty period. The purchaser, of this RelaxPak™ assumes liability for the consequence of its misuse by himself or others, including any use by persons whose treatment is not under the supervision or at the direction of a physician as required by Federal Law.

This warranty and the remedies given herein, is in lieu of all others either expressed or implied.

Date of Purchase_____

RelaxPak Accessories Reorder Form

Hints on proper care

The RelaxPak is relatively maintenance free in the course of normal use, other than the occasional need to change the batteries. Should the user wish to clean the case or other external parts, a soft cloth dipped in warm soapy water and wrung out prior to use should suffice to clean the outside of the case. Never dip the unit into water or liquid while cleaning since this may stop or significantly alter the working of the electronic parts inside. The bilateral electrodes may be cleaned in warm, soapy water and rinsed in clear water before placing them in circulating air to dry.

Never use harsh household detergents or special cleansers on either the case or the electrodes. Similarly, never use gasoline, turpentine, paint thinner or dry cleaning fluids when cleaning the unit or the electrodes. Should questions arise regarding the proper care of your RelaxPak, contact our consumer services representative at our home office address or call (214) 217-5418.

Specifications

The RelaxPak is powered by two, nine volt batteries and puts out an alternating current sine wave (~) 100 times each second, with .002 seconds rest between each sine wave burst. The maximum amount of current you can receive is .001 ampere, or about that required to run a flashlight...not enough to hurt you in any way, but enough to render very effective treatment for the conditions indicated.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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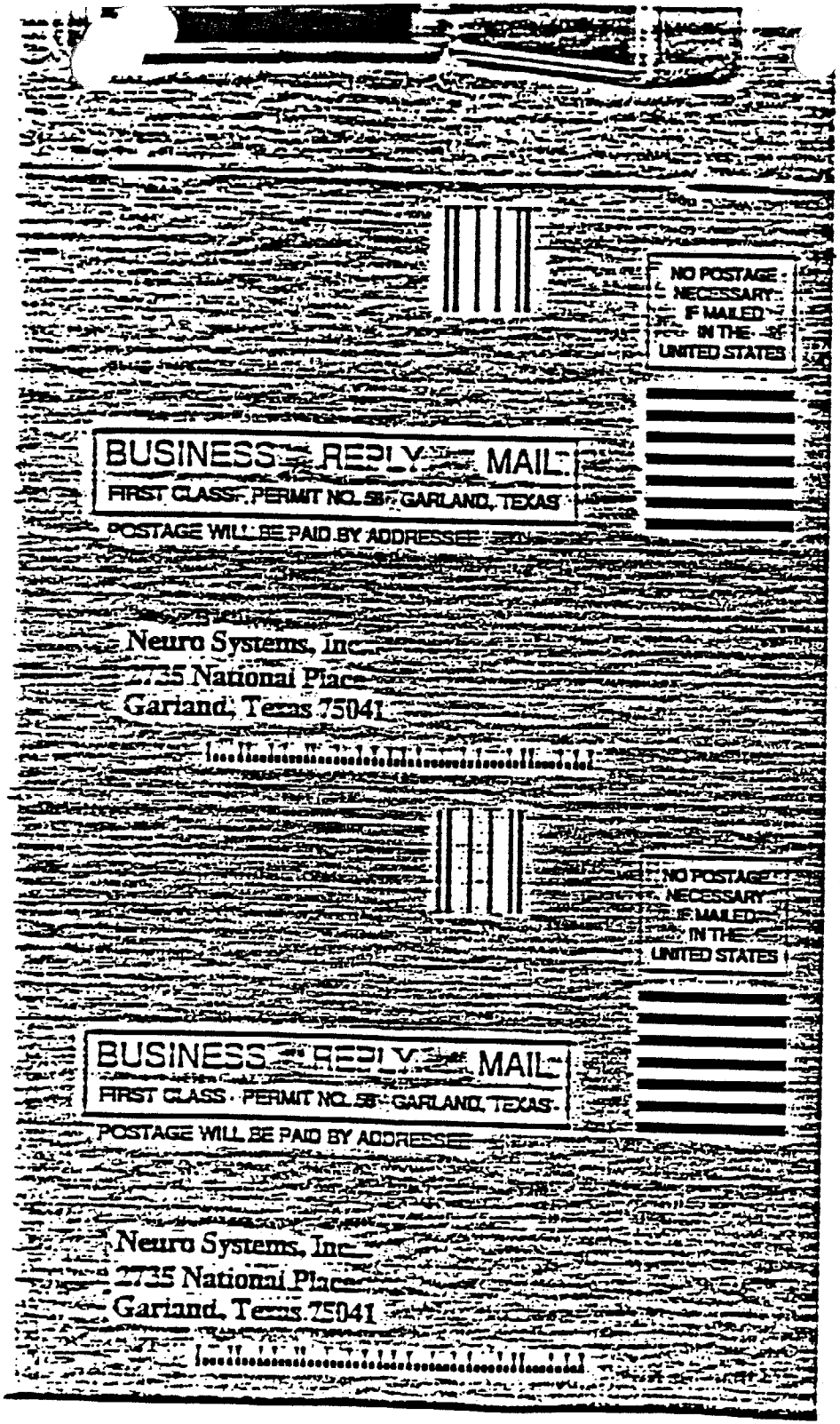

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BUSINESS REPLY MAIL
FIRST CLASS PERMIT NO. 58 GARLAND, TEXAS

POSTAGE WILL BE PAID BY ADDRESSEE

Neuro Systems, Inc.
2735 National Plac
Garland, Texas 75041

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Neuro Systems, Inc.
2735 National Plac
Garland, Texas 75041

RelaxPak Accessories Reorder Form

Catalogue No.	No.	Amount
1038 Bilateral electrodes at $25.00 ea.		
1040 3/4" Rubber electrodes at $10.00pr.		
1043 36" Electrode wire leads at $8.00 ea.		
1103 Electrode jell #202 tube $1.50 ea.		
1092 Tape Disc (50/per pkg.) @ $5.00 per pkg.		

Name _____ Total _____

Address _____

Zip _____

Warranty Registration Card

Model: RelaxPak™

Serial No: 1152

Date of purchase _____

Prescribing Physician _____

Name _____ Phone No. _____

Address _____

Zip _____

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EXHIBIT E

Chart of Similarities

* LISS Cranial Stimulator
  [Zero DC]
* Neurotone

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CHART OF SIMILARITIES

Criteria	LISS Cranial Stimulator	Neurotone Model No. 101
Waveform	Square wave	Sine wave
Type	Bipolar Assymmetrical	Bipolar Assymmetrical
Burst Duty cycle	75% On time	20% On time
On Time Milliseconds	50	2
Frequency,hz	15,000-carrier modulated by 15, modulated by 500	1,000-carrier modulated by 100
Current, Milliamperes	0-4 peak	0-1.5
Treatment Time, Minutes	10 to 20	30
Indications	Symptomatic Relief of Anxiety, Depression, & Insomnia	Symptomatic Relief of Anxiety, Depression,& Sleeping Problems
Maximum Charge Per Pulse, Microcoulombs	0.133	0.750

Summary of output charact. as compared w/ Neurotone 101

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