Pharmaceutical Innovations, Inc.
c/o Shirley J. Bergman
Vice President
897 Frelinghuysen Ave.
NEWARK, NJ 07114

january 9, 2018

Re: K163027
Trade/Device Name: Ultra/Phonic Free® Conductivity Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: MUI
Dated: December 8, 2017
Received: December 13, 2017

Dear Ms. Bergman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163027

Device Name

Ultra/Phonic® Free Conductivity Gel

Indications for Use *(Describe)*

Ultra/Phonic® Free Conductivity Gel is intended for general use as a non-sterile transmission media for acoustically coupling a transducer to a human body surface during external therapeutic and diagnostic ultrasound imaging procedures. It is placed on the patient's skin or on the transducer prior to initiating an ultrasound examination.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PHARMACEUTICAL INNOVATIONS, INC.
PRESIDENT OF THE UNITED STATES HIGHEST AWARD FOR EXCELLENCE IN EXPORTING
897 Frelinghuysen Avenue · Newark, New Jersey 07114-2195 · (973) 242-2900 · Fax: (973) 242-0578

510(k) Summary

Ultra/Phonic® Free Conductivity Gel

I. SUBMITTER

Pharmaceutical Innovations, Inc.
897 Frelinghuysen Ave.
Newark, New Jersey 07114-2195
Phone: (973) 242-2900 Fax: (973) 242 0578
Contact Person: Ms. Shirley J Bergman Vice President.

Date Prepared: Friday, October 21, 2016

II. DEVICE

Name of Device: Ultra/Phonic® Free Conductivity Gel

Classification Name: Diagnostic ultrasonic transducer (accessory) (21 CFR § 892.1570)

Regulatory Class: II

Product Code: MUI

III. PREDICATE DEVICE

Device Name: Sonishield™ 100 Antimicrobial Ultrasound Gel

Classification Name: Diagnostic ultrasonic transducer/acoustic gel (21 CFR § 892.1570)

Regulatory Class: II

Product Code: MUI

510K Number: K151070

Reference Device: Ecogel 100 Ultrasound Gel

Classification Name: Diagnostic ultrasonic transducer. (21 CFR 892.1570)

Regulatory Class: II Product Code: ITX

510K Number: K961757

PHARMACEUTICAL INNOVATIONS, INC.
PRESIDENT OF THE UNITED STATES HIGHEST AWARD FOR EXCELLENCE IN EXPORTING
897 Frelinghuysen Avenue · Newark, New Jersey 07114-2195 · (973) 242-2900 · Fax: (973) 242-0578

IV. DEVICE DESCRIPTION

Ultra/Phonic® Free Conductivity Gel is an aqueous, non-sterile ultrasound conducting medium for use during non-invasive ultrasonic medical procedures. It is placed between the ultrasound transducer and the patient, eliminating air at the contact surface while providing lubrication. This provides an acoustic pathway between the transducer and the skin. This uninterrupted pathway allows the transducer to send sound waves which enter the body, and to receive echoes from tissues and structures without unexpected interference. When the echoes are received by the scanner, it analyzes them to determine how strong they are, and how long they took to be received after transmission. That information is then processed and outputted to a display as an image which is used for diagnostic and therapeutic purposes by health care professionals.

It is packaged in 5L Cubitainers and 250 mL bottles.

Major characteristics include:

- Non-sensitizing, non-irritating
- Water soluble, non-staining, and easily cleanable
- Does not contain oil or fatty matter
- Does not damage the probe
- pH level is 6.25 ± 0.25 @ 25°C
- Resists thinning and decomposition when exposed to perspiration and body heat
- Sheer thinning gel is easy to apply, but doesn't run or drip
- High viscosity allows for thick application, adapting to contours and hair to minimize interference

V. INDICATIONS FOR USE

The Indications for Use statement is as follows:

Ultra/Phonic® Free Conductivity Gel is intended for general use as a non-sterile transmission media for acoustically coupling a transducer to a human body surface during external therapeutic and diagnostic ultrasound imaging procedures. It is placed on the patient's skin or on the transducer prior to initiating an ultrasound examination. It is indicated for prescription use only.

PHARMACEUTICAL INNOVATIONS, INC.
PRESIDENT OF THE UNITED STATES HIGHEST AWARD FOR EXCELLENCE IN EXPORTING
897 Frelinghuysen Avenue · Newark, New Jersey 07114-2195 · (973) 242-2900 · Fax: (973) 242-0578

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Ultra/Phonic® Free Conductivity Gel has substantially the same technological characteristics as the predicate device, as well as the reference device. The three are compared below:

Subject	Ultra/Phonic® Free Conductivity Gel	Sonishield™ 100 Antimicrobial Ultrasound Gel	Ecogel 100 Ultrasound Gel
Intended Use	External	External	External
Ingredients	Salt free	Salt free	Salt free
	Dye Free	Dye free	Green coloring*
	Alcohol free	Alcohol free	Alcohol free
	Formaldehyde free	Formaldehyde free	Formaldehyde free
	Perfume Free	Perfume free	Perfume free
Physical Properties	Twist cap for accurate dispensing (Snap-top on Cubitainers)	Twist cap for accurate dispensing	Twist cap for accurate dispensing
	Twist-off top for quick refilling.	Flip-top can for quick refilling	Flip-top can for quick refilling
Chemical Properties	High clarity	Very high clarity	Good clarity
	Bacteriostatic, nonsensitizing	Hypoallergenic, bacteriostatic, nonsensitizing	Hypoallergenic, bacteriostatic, nonsensitizing
	pH 6.25 ± 0.25	pH 4.5 – 6.5	pH 6.5 ± 0.75
	Density (g/mL) = 1.018	Density (g/mL) = 1.009	Density (g/mL) = 0.99
	Stabilized, high viscosity formulation resists melting and decomposition from body heat and perspiration, providing lasting conductivity with zero or minimal reapplication.	Very clear screen image with high viscosity and vacuum process. No rapid melting from high viscosity gel.	It has low viscosity. It melts immediately from low viscosity
	Viscosity 600,000 ± 300,000 CPS	Viscosity 80,000 – 120,000 CPS	Viscosity 35,000 – 40,000 CPS
	Boiling Point > 200° C	Boiling point > 200° C	Boiling point 100° C
	Water soluble high MW polymers	Water soluble high MW polymer	Water soluble high MW polymer
	No irritation	No irritation	No irritation
Process	Normal process	It has a rapid manufacturing process	Normal process
	Standard bottle (Cubitainers for refilling)	Sonishield™ employs a soft bottle for ease of use.	Standard bottle

PHARMACEUTICAL INNOVATIONS, INC.
PRESIDENT OF THE UNITED STATES HIGHEST AWARD FOR EXCELLENCE IN EXPORTING
897 Frelinghuysen Avenue · Newark, New Jersey 07114-2195 · (973) 242-2900 · Fax: (973) 242-0578

Subject	Ultra/Phonic® Free Conductivity Gel	Sonishield™ 100 Antimicrobial Ultrasound Gel	Ecogel 100 Ultrasound Gel
	Normal process	Sonishield™ production employs a closed-loop system so there is no pollution transmission. Product is manufactured very cleanly	Normal process
	Standard production area	Standard production area	Standard production area
	Standard process manufactured to release specifications.	Standard process manufactured to release specifications.	Standard process
Label	Standard information	Standard information on polyethylene label to prevent loss of lettering	Standard information
Design	Conical cap on bottles. Snap top cap on Cubitainers.	Bottle diameter designed to be compatible with ultrasound device. Bottle cap is designed for ease of opening and closing with one hand.	Conical cap
Safety	Ultra/Phonic® Free Conductivity Gel label contains appropriate warnings and characteristics	Sonishield™ label contains appropriate warnings and characteristics (Latex free, PVC-free)	Standard information
Environment of Use	Hospital	Hospital	Hospital
Target Population	Pediatric and adult	Pediatric and adult	Pediatric and adult
Use	Multiple Uses	Multiple uses	Multiple uses
Material (Package)	Polyethylene	Polyethylene	Polyethylene
Patient Contact Materials	Probe	Probe	Probe
Energy Type	Electricity only for the ultrasound device	Electricity only for the ultrasound device	Electricity only for the ultrasound device

* The predicate device 510K (K151070) summary lists Ecogel 100 as not containing dye, while the Konix Ultrasound Gel (K101952) 510K summary, which also used Ecogel 100 as a predicate, lists Ecogel 100 as being dyed green. It is in fact, dyed green.

PHARMACEUTICAL INNOVATIONS, INC.
PRESIDENT OF THE UNITED STATES HIGHEST AWARD FOR EXCELLENCE IN EXPORTING
897 Frelinghuysen Avenue · Newark, New Jersey 07114-2195 · (973) 242-2900 · Fax: (973) 242-0578

VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

Non-clinical performance

Ultra/Phonic® Free Conductivity Gel was evaluated for its acoustic performance. Results indicate that the acoustic properties of the gel are:

1. Virtually identical to that of human skin.
2. Similar to other coupling gels commonly used in the United States.

The acoustic properties of Ultra/Phonic® Free Conductivity Gel and Sonishield™ 100 Antimicrobial Ultrasound Gel are as follows:

Property	Ultra/Phonic® Free Conductivity Gel	Sonishield™ 100 Antimicrobial Ultrasound Gel
Sound velocity (m/sec)	1488 ms^{-1} at 22.5°C	1497 ms^{-1} at 30°C
Density (kg/m3)	1018 kg/ m^{-3} at 22.5°C	1023 kg/ m^{-3} at 30°C
Acoustic impedance (kg/m2 sec)	1.51 MRayls at 22.5°C	1.53 MRayls at 30°C
Attenuation coefficient as a function of frequency, a/f (dB/cm-MHz)	$0.0185 + 0.01335\ f^{1.0894}$	$0.04 \pm 0.0042\ f$

The acoustic properties of the predicate gel and Ultra/Phonic® Free Conductivity Gel are virtually identical. Although the analysis was conducted at different temperatures, both are well within the range of temperatures encountered during clinical use (72.5°F - 80°F). Such variations in temperature do not induce more than small changes in the listed acoustic properties, too small to alter performance, or cast doubt upon the conclusions of this comparison.

The USP <51> (Category 2) Antimicrobial Effectiveness Test passed with log reductions greater than 5 for all 14 and 28 day bacterial (*Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Pseudomonas aeruginosa* ATCC 9027) counts. Yeasts and molds (*Aspergillus brasiliensis* ATCC 16404, *Candida albicans ATCC* 10231) did not increase from initial counts, and in fact considerably decreased.

Animal Testing

Biocompatibility (ISO 10993-10) testing was conducted for Skin Irritation and Skin Sensitization. Conclusions from these studies: Ultra/Phonic® Free Conductivity Gel was found to be non-sensitizing and non-irritating.

PHARMACEUTICAL INNOVATIONS, INC.
PRESIDENT OF THE UNITED STATES HIGHEST AWARD FOR EXCELLENCE IN EXPORTING
897 Frelinghuysen Avenue · Newark, New Jersey 07114-2195 · (973) 242-2900 · Fax: (973) 242-0578

In Vitro Cytotoxicity:

Cytotoxicity (ISO 10993-5:2009) testing was conducted.

Conclusion from this study: The test article does not meet the requirement of the test as per The International Organization for Standardization (ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for the *In Vitro* Cytotoxicity, Reference Number ISO 10993-5:2009), and *is considered cytotoxic*.

Further testing was conducted to establish the safety of the product. The results of the Human-Repeated-Insult-Patch-Test (RIPT) indicated no potential for dermal irritation or allergic contact sensitization. The results of the RIPT test, combined with the favorable results associated with the sensitization and irritation assays, demonstrate the safety of this product.

VIII. CONCLUSIONS

The above-referenced comparisons of the technological and non-clinical performance characteristics indicate that the Ultra/Phonic® Free Conductivity Gel is comparable to its predicate and reference devices and certainly substantially equivalent to them and other ultrasonic coupling gels commonly used in the United States today.