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510(k) Summary

NeutroPhase® Skin and Wound Cleanser OTC

Submitter Name:	NovaBay Pharmaceuticals, Inc.
Submitter Address:	5980 Horton Street, Suite 550 Emeryville, CA 94608
Contact Person:	Keith Bley, Ph.D. Senior Vice President of Product Development
Phone Number:	650.861.0388
Fax Number:	510.225.0371
Date Prepared:	May 23, 2013
Device Name:	NeutroPhase® Skin and Wound Cleanser OTC
Common Name	Wound Cleanser
Classification Name: Classification #: Product Code: Classification Panel:	Dressing, Wound, Drug Unclassified (Pre-amendment) FRO General and Plastic Surgery
Predicate Devices:	K113820, NeutroPhase® Skin and Wound Cleanser, NovaBay Pharmaceuticals, Inc. K090206, Oculus Puracyn™ Skin and Wound Cleanser with Preservatives, Oculus Innovative Sciences, Inc.
Indications for Use Statement:	NeutroPhase® Skin and Wound Cleanser OTC is intended for the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.
Device Description: Design and Summary of Technological Characteristics	NeutroPhase® Skin and Wound Cleanser OTC is a clear, liquid solution cleanser and wound dressing that was previously cleared by FDA for Rx Use only. The device for OTC use is exactly the same as the Rx product. It is composed of hypochlorous acid (HOCl) 0.01% in saline. As a known antimicrobial, it inhibits growth of microorganisms in solution. The cleanser is provided in a glass bottle; a pump attachment for use in spraying the cleanser on wounds is also provided.
Testing:	The antimicrobial activity in solution of the product is documented by extensive testing performed both by NovaBay and certified test laboratories to the criteria specified in USP <51> *Antimicrobial Effectiveness Test*; effectiveness against the following organisms has been shown in this testing: bacteria: *Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus;* and fungi: *Candida albicans, Aspergillus niger.* Stability testing supports a shelf life of 24 months for the NeutroPhase® Skin and Wound Cleanser OTC.

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	The biocompatibility testing required for this category of body contact device, according to ISO 10993, has been performed with results establishing the NeutroPhase® product is safe, biocompatible and non-toxic for the use intended.
Comparison to the Predicate Devices:	The NeutroPhase® Skin and Wound Cleanser OTC has the same intended use as the predicate Puracyn™ cleanser and a similar intended use as the NeutroPhase® Rx Only product. The NeutroPhase® Skin and Wound Cleanser OTC has the same ingredients as the NeutroPhase® predicate and is similar to the Puracyn™ predicate in that both contain hypochlorous acid as a preservative in solution. The new NeutroPhase® cleanser is manufactured by the same contract manufacturer and under the same processes as the predicate NeutroPhase® cleanser.
Conclusion regarding Substantial Equivalence:	Based on the above and the documentation in the 510(k) the NeutroPhase® Skin and Wound Cleanser OTC is substantially equivalent to both predicate devices.
Verifications regarding this 510(k) Summary:	The summary includes only information that is also covered in the body of the 510(k). The summary does not contain any puffery or unsubstantiated labeling claims. The summary does not contain any raw data, i.e., contains only summary data. The summary does not contain any trade secret or confidential commercial information. The summary does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

NovaBay Pharmaceuticals, Incorporated
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Ms. Patsy J. Trisler, JD, RAC
Regulatory Consultant
5600 Wisconsin Avenue, #509
Chevy Chase, Maryland 20815

July 24, 2013

Re: K131542
Trade/Device Name: NeutroPhase® Skin and Wound Cleanser OTC
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 23, 2013
Received: May 31, 2013

Dear Ms. Trisler:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K131542

Device Name: NeutroPhase® Skin and Wound Cleanser OTC

Indications for Use:

NeutroPhase® Skin and Wound Cleanser OTC is intended for the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.

Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131542