NovaBay Pharmaceuticals, Inc
Response to Request for Additional Information

SEP 28 2007

Revision to 510(k) summary - pages 028-029

510(k) Summary
Prepared April 11, 2007 (Revised September 19, 2007)

Submitted by: NovaBay Pharmaceuticals
5980 Horton Street
Suite 550
Emeryville, California 94608

Contact Person: Behzad Khosrovi Ph.D.
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Product Name: NeutroPhase™

Common Name: Liquid bandage/wound cleanser

Classification: KMF 880.5090 Class II

Predicate Devices:

Device Name	*Manufacturer*	*K Number*
Dermacyn Wound Care	***Oculus Innovative Sciences, Inc***	***K060113***
Dermacyn Wound Irrigation	***Oculus Innovative Sciences, Inc..***	***K042729***

Description of Device:
NeutroPhase™ is a wound cleansing solution for irrigating and cleansing of dermal wounds. The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of foreign objects such as dirt and debris.

Intended Use:
The device is intended for moistening absorbent wound dressings and irrigating and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. It is also intended for moistening, debriding and irrigating acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, leg ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, abrasions and minor irritations of the skin.

Comparison with Predicate Devices:
The submission device and the predicate devices have substantially equivalent intended use and technological specifications.

Performance:
The NeutroPhase™ verification testing has confirmed the device's conformance with specifications. The functional specifications do not include any significant differences from those of the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2007

NovaBay Pharmaceuticals, Inc.
% Behzad Khosrovi Ph.D.
Vice President of Research and Development
5980 Horton Street, Ste. 550
Emeryville, California 94608

Re: K071056
Trade/Device Name: NeutroPhase™ Wound Cleanser
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: September 18, 2007
Received: September 20, 2007

Dear Mr. Khosrovi:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

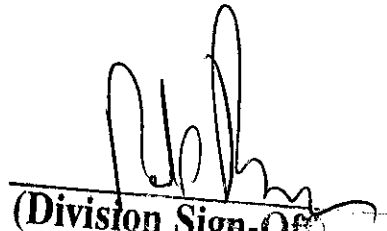
Revision to FDA Indications for use form- pages 012

510(k) Number (if known):

Device Name: NeutroPhase™ Wound Cleanser

Indications For Use:

The device is intended for moistening absorbent wound dressings and irrigating and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. It is also intended for moistening, debriding and irrigating acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, leg ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, abrasions and minor irritations of the skin.



(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K071056

Prescription Use____X____ OR Over-The-Counter Use _____
(Per 21CFR 801)

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

_____Concurrence Of CDRH, Office Of Device Evaluation (ODE)