K081009

510(k) Summary
Prepared March 28, 2008

MAY 20 2008

Submitted by: NovaBay Pharmaceuticals, Inc.
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Product Name: NeutroPhase Wound Cleanser

Common Name: Liquid bandage/wound cleanser

Classification: KMF 880.5090 Class I

Predicate Devices: The modified NeutroPhase is substantially equivalent to NeutroPhase (K071056)

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. The device is offered in various bottle sizes.

Intended Use:
The device is intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. It is also intended for moistening and debriding 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 modified device represents a minor change to the predicate specification. The submission device and the predicate device have the same intended use and substantially equivalent technological specifications.

Performance:
The NeutroPhase verification testing under the company's Design Control Process has confirmed the device's conformance with specifications. The specifications do not include any significant differences from those of the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Novabay Pharmaceuticals, Inc.
% Ms. Sheila W. Pickering, Ph.D.
Regulatory Affairs Consultant
5980 Horton Street, Suite 550
Emeryville, California 94608

MAY 20 2008

Re: K081009
Trade/Device Name: Modified NeutroPhase Wound Cleanser
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: April 4, 2008
Received: April 8, 2008

Dear Dr. Pickering:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

510(k) Number (if known): K081009

Device Name: Modified NeutroPhase Wound Cleanser

Indications For Use:

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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)

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

510(k) Number K081009