K072876
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510(k) SUMMARY

JUN 19 2008

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Rebecca Stolarick Director, Regulatory Affairs
Phone: (610) 596-2536
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DEVICE NAME: Prontosan™ Wound Irrigation Solution

COMMON OR USUAL NAME: Wound Cleanser, Wound Dressing

DEVICE CLASSIFICATION: Class II, Product Code FRO, Unclassified

PREDICATE DEVICES: Dermacyn® Wound Care solution
Oculus Innovative Sciences, Inc.
Regulatory Class: Unclassified, Product Code: FRO
510(k) K060113 March 19, 2007

DESCRIPTION: Prontosan Wound Irrigation Solution is a clear, colorless liquid containing undecylenamidopropyl betaine, polyaminopropyl biguanide, sodium hydroxide and purified water. The solution is aseptically filled using a blow fill seal process into low density polyethylene 40 mL ampoules and 350 mL squeeze bottles with screw caps. Prontosan Wound Irrigation Solution is used for cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, burns, post-surgical wounds and abrasions. The mechanical action of moving across the wound provides for the mechanism of action and aids in the removal of foreign material such as dirt and debris.

INTENDED USE: Prontosan Wound Irrigation Solution is intended for cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, burns, post-surgical wounds and abrasions.

SUBSTANTIAL EQUIVALENCE:

The proposed device and the predicate device have similar indications for use. The safety and effectiveness of Prontosan™ Irrigation Solution is supported by biocompatibility testing, functional performance testing and shelf life testing conducted with the proposed device. Comparison testing conducted with Prontosan Wound Irrigation Solution and Dermacyn® Wound Care solution demonstrated that Prontosan Wound Irrigation Solution, the proposed device is similar to Dermacyn Wound Care solution, the predicate device. This testing also demonstrates that there are no new issues of safety and effectiveness for the proposed device. Prontosan Wound Irrigation Solution and Dermacyn Wound Care solution are both intended for cleaning and irrigating wounds and moistening wound dressings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2008

B. Braun Medical, Inc.
% Ms. Rebecca Stolarick
Director, Regulatory Affairs
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K072876
Trade/Device Name: Prontosan™ Wound Irrigation Solution
Regulation Number: Unclassified
Product Code: FRO
Dated: June 9, 2008
Received: June 11, 2008

Dear Ms. Stolarick:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K072876

Device Name: Prontosan™ Wound Irrigation Solution

Indications For Use: Prontosan Wound Irrigation Solution is intended for cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, burns, post-surgical wounds and abrasions.

Prescription Use X AND/OR Over-The-Counter Use

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

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

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