5. 510(k) SUMMARY

DATE: October 15, 2010

NOV - 3 2010

SUBMITTER:

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

Contact: Matthew J. Homa, Sr. Analyst, Regulatory Affairs
Phone: (610) 596-2558
Fax: (610) 266-4962
E-mail: matthew.homa@bbraun.com

DEVICE NAME: Prontosan® Wound Gel

COMMON OR USUAL NAME: Wound Cleanser, Wound Dressing

DEVICE CLASSIFICATION: Class II, Product Code FRO, Unclassified

PREDICATE DEVICES: Prontosan® Wound Gel, B. Braun Medical, Inc., K090141 Class II, FRO, Unclassified
Anasept® Antimicrobial Skin and Wound Gel, Anacapa Technologies, Inc., K073547, Class II, FRO, Unclassified

DESCRIPTION: Prontosan® Wound Gel is a clear, colorless and virtually odorless gel containing undecylenamidopropyl betaine, polyaminopropyl biguanide, glycerol, hydroxyethylcellulose and purified water. Prontosan Wound Gel is a non-pyrogenic solution used for wound management that is sterile by aseptic manufacturing until the product is first opened. PHMB is added to the product in the concentration of 0.1% w/w as a preservative to inhibit the growth of microorganisms within the product.

Prontosan Wound Gel will be offered in an over-the-counter (OTC) version and a professional use (Rx only) version. Prontosan Wound Gel is used to moisten the wound bed and clean the wound surface, including those that are difficult to access. Prontosan Wound Gel is aseptically filled into a 30 mL low density polyethylene squeeze bottle with a screw cap.

INTENDED USE:

OTC Use: Prontosan Wound Gel is intended to cleanse and moisten the wound bed and for the management of minor cuts, abrasion, laceration, and minor burns.

Professional Use: Prontosan Wound Gel is intended to cleanse and moisten the wound bed and for the management of ulcers, 1st and 2nd degree burns, partial and full thickness wounds, and surgical incisions. It can be used during wound dressing changes to soften encrusted wound dressings.

SUBSTANTIAL EQUIVALENCE:

Two predicate devices are utilized for substantial equivalence, Prontosan® Wound Gel (K090141) and Anasept® Antimicrobial Skin and Wound Gel (K073547). Prontosan Wound Gel has an intended use similar to Anacapa Technologies' Anasept® Antimicrobial Skin and Wound Gel, i.e., to remove foreign matter , and Anasept® Antimicrobial Skin and Wound Gel is also labeled for OTC use.

Prontosan Wound Gel is the same product as in the original Prontosan Wound Gel submission, K090141. Both of these gels are comprised of the same ingredients and are processed and filled in the same manner. The biocompatibility and functional performance testing conducted on Prontosan Wound Gel in K090141 is applicable to this submission. The only difference between Prontosan Wound Gel, K090141, and this submission is the indications and intended use.

CONCLUSION:

In-vitro testing was conducted to demonstrate the effectiveness of the preservative in Prontosan® Wound Gel and substantial equivalence with predicate device, Anasept® Antimicrobial Skin and Wound Gel. The non-clinical testing conducted with the proposed device demonstrates that the proposed device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

B. Braun Medical Inc.
% Mr. Matthew J. Homa
Senior Analyst, Regulatory Affairs
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

NOV - 3 2010

Re: K101882
Trade/Device Name: Prontosan® Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 17, 2010
Received: September 20, 2010

Dear Mr. Homa:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K101882

NOV - 3 2010

Device Name: Prontosan® Wound Gel

Indications For Use:

OTC Use: Prontosan Wound Gel is intended to cleanse and moisten the wound bed and for the management of minor cuts, abrasion, laceration, and minor burns.

Professional Use: Prontosan Wound Gel is intend to cleanse and moisten the wound bed and for the management of ulcers, 1st and 2nd degree burns, partial and full thickness wounds, and surgical incisions. It can be used during wound dressing changes to soften encrusted wound dressings.

Prescription Use X OR Over-The-Counter Use X
(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)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101882