SEP 1 9 2001

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92."

"The assigned 510(k) number is: K011975 *."*

1. Submitter Information: **June 20, 2001**

B. Braun Medical Inc.
1601 Wallace Drive Ste. 150
Carrollton, TX. 75006
(972) 245-2243

Contact Person: Ms. Linda Morgan, RN, BSN
Regulatory Affairs
Phone: 972.245.2243 ext. 339
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2: Name of Device: **Infusion Pump**

Trade Name: **Horizon Outlook™ with DoseCom™**

Classification Name: **Class II, 80FRN**
21 CFR 880.5725

3: Predicate Device:

The predicate device that B. Braun Medical Inc. is claiming substantial equivalence[1] to is the Horizon Outlook™ with DoseScan™, (formerly named Horizon® Lite) marketed under cleared 510(k)994375 by B. Braun Medical Inc. Horizon Outlook™ with DoseScan™ is an electrical, external, volumetric infusion pump. There are no new issues of safety or effectiveness raised by the new Horizon Outlook™ with DoseCom™.

[1] The term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view

under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

4: Description of the Subject Device:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Medical Inc. intends to introduce into interstate commerce the Horizon Outlook™ with DoseCom™ Infusion Pump. The Outlook™ with DoseCom™ is an external volumetric infusion pump that is suitable for dispensing liquids indicated for use with infusion therapy. The system created by using dedicated cassettes is intended to provide accurate and continuous flow of these fluids to the patient. The pump is software controlled and operates using volumetric displacement with a stepper-motor mechanism.

The infusion pump contains the following hardware assemblies: volumetric displacement / stepper motor pumping mechanism assembly, power supply assembly, pole clamp assembly, display assembly, electronics assembly and a wireless PCMCIA network card. The battery power supply consists of rechargeable 12 volt battery. The display subassembly contains an LCD display and a keypad used to input data into the pump as well as to present pump status and information to the user.

The electronics subassembly contains all of the electronics in the pump, including the microprocessors that run the software. The electronics subassembly also contains communications electronics that will allow the pump to transmit and receive messages to and from external devices, including personal computers, personal digital assistants (PDA), hospital monitoring systems and hospital information management systems (HIMS).

The software provides communication capabilities from the pump to external communication devices. This includes transmission of the following information: Operation / Alarm Log, pump status and pump configuration / calibration data. The software also provides the ability to customize pump features by downloading from external devices to the pump. This feature is only accessible by a trained Biomedical Technician.

5: Intended Use of the Subject Device:

The system created by using the Outlook™ with DoseCom™ with dedicated cassettes is intended to provide accurate and continuous flow of parenteral fluids

to the patient. The pump is software controlled and operates using a volumetric displacement / stepper motor pumping mechanism.

The Horizon Outlook™ with DoseCom™ is intended for but not limited to use in the hospital, and/or nursing home (extended care) settings. The Operation Manual is intended to reinforce the teaching given to the user by a trained healthcare professional or an authorized B. Braun Medical Inc. representative. A trained Biomedical Technician must perform a full set-up of the pump before use in a clinical setting.

The new incorporation of DoseCom™ allows for wireless communication between the infusion pump and the hospital information management system (HIMS). The Horizon Outlook™ with DoseCom™ is intended to provide a way to automate the programming of infusion parameters, thereby decreasing the amount of manual steps necessary to enter infusion data. All data entry and validation of infusion parameters using the Outlook™ with DoseCom™ is performed by the trained healthcare professional according to a physician's order.

6: Technological Characteristics of the Subject Device

The subject device, Horizon Outlook™ with DoseCom™ is substantially equivalent to the predicate device, the Horizon Outlook™ with DoseScan™. The subject and predicate devices are similar in design, material composition, components, manufacturing process, intended use and labeling. The substantial equivalence claim between the subject and predicate device is supported by the information and data provided in this 510(k) submission.
This includes the following information:

- Description of the subject and predicate devices.
- Intended use of the subject and predicate devices.
- Material composition of the subject and predicate devices.
- Labels and labeling for the subject and predicate devices.
- Comparison tables of attributes and specifications of the subject and predicate devices.
- Subject device customer functional specification.
- Subject device system and software hazard analysis.
- Subject device system and software requirements.
- Subject device system and software test plans.
- Subject device system and software test matrix.

7: Signature of Applicant

B. Braun Medical Inc.
Linda Morgan, RN, BSN
Regulatory Affairs Specialist

Signature _____ Date _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Ms. Linda Morgan
Regulatory Affairs Specialist
B. Braun Medical, Incorporated
1601 Wallace Drive, Suite 150
Carrollton, Texas 75006

Re: K011975
Trade/Device Name: Horizon Outlook™ with DoseCom™
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: June 20, 2001
Received: June 25, 2001

Dear Ms. Morgan:

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 (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number: K011975

Device Name: Horizon Outlook™ with DoseCom™

Indications For Use:

The Horizon Outlook™ with DoseCom™ is an electrical, external volumetric infusion pump intended to provide infusions of parenteral fluids. Parenteral fluids may include all standard fluids and/or medications indicated for infusion as well as blood and blood products. Adjustable occlusion pressure settings allow arterial, epidural and intrathecal infusions. The system created by using dedicated cassettes is intended to provide accurate and continuous flow of these fluids to the patient.

The Horizon Outlook™ with DoseCom™ is intended to provide a way to automate the programming of infusion parameters, thereby decreasing the amount of manual steps necessary to enter infusion data. All data entry and validation of infusion parameters is performed by the trained healthcare professional according to a physician's order.

The Horizon Outlook™ with DoseCom™ is intended for but not limited to use in the hospital, and/or nursing home (extended care) settings. The Horizon Outlook™ with DoseCom™ is intended for use by trained healthcare providers in accordance with the instructions provided in the Operation Manual.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter Use _____
(Per 21 CFR 801.109)

Patricia Cascade
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011975