MAR - 8 2000

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: K994375 *."*

1. Submitter Information: **December 20, 1999**

B. Braun Medical Inc.
1601 Wallace Drive Ste. 150
Carrollton, TX 75006

Contact Person: Mr. Gary A. Gulyas
Quality Manager
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2: Name of Device: **Infusion Pump**

Trade Name: **Horizon® Lite**

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® Modular Infusion System, currently marketed by B. Braun Medical Inc. under cleared 510(k) K904518.

The Barcode Reader that B. Braun Medical Inc. is claiming substantial equivalence to is part of the Verifuse® Multi-Mode Ambulatory Infusion Pump, marketed by Block Medical under cleared 510(k) K934551.

[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. proposes to modify the predicate device by The predicate device has been modified to create the Horizon® Lite. The case top and bottom have been modified to produce a newer, smaller profile and thereby decreasing the total weight. The material composition will not change. The main board and power supply board have been upgraded from through-hole to surface mounted technology. Modifications will be made to support a hardwire RS232 instead of the optical RS232 currently in the predicate device. The RAM has been increased to 512K. An LCD will replace the existing seven segment LED. LCD technology has been updated for increased visibility. The Air-in-Line has been upgraded to an ultrasonic detector.

The subject pump is also different from the predicate in that it incorporates the use of a Barcode Reading and Labeling System. The new incorporation of the B. Braun Medical Barcode Reading and Label Generating System is intended to decrease the incidence of medication errors by reducing the amount of steps necessary to program the pump. The Barcode Reader provides a method to automate the implementation of an infusion by verifying nurse and patient identifications and transferring infusion parameters to the pump.

The Barcode Reading and Label Generating System allows a pharmacist or authorized user to enter patient identification, medication and infusion parameters into a computer format. This information is printed in a barcode format and placed on the medication container. Infusion parameters are then transferred into the pump by scanning the barcode. The patient data on the container must match the patients' personal identification label. The nurse must also scan his/her personal identification barcode. Access is denied if all patient and nurse identifiers are not verified. The user must then manually enter infusion data.

The Barcode Reader in the Horizon® Lite can only read barcode labels produced by the B. Braun Barcode Generating System software, that is provided with the pump.

The infusion pump contains the following hardware assemblies: swivel-drive pumping mechanism assembly, power supply assembly, pole clamp assembly, display assembly, and electronics assembly. 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 and hospital monitoring systems.

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 communication abilities from external devices to the pump. These features are only accessible by a trained Biomedical Technician. Programming of the pump is to be performed by trained biomedical professionals. The pump's software does not allow for the capability to control rate, volume or therapy information from external devices.

5: Intended Use of the Subject Device:

The Horizon® Lite is an electrical, external volumetric infusion pump that provides infusions of parenteral fluids. The pump may be used to infuse all intravenous medications, blood, and blood components. 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 pump is software controlled and operates using volumetric displacement with a stepper-motor mechanism.

The new incorporation of a Barcode Reading System is intended to decrease the incidence of medication errors. The Barcode Reader provides a method to automate the implementation of an infusion by verifying nurse and patient identifications and transferring infusion parameters to the pump.

The Horizon® Lite is intended for but not limited to use in the hospital, home care and/or nursing home (extended care) settings. The Horizon® Lite is intended for use by trained healthcare providers in accordance with the instructions provided in the Operation Manual. All data entry and validation of the Horizon® Lite is performed by the trained healthcare provider per a physician's order.

6: Technological Characteristics of the Subject Device

The subject device, Horizon® Lite is substantially equivalent to the predicate device, the Horizon® Modular Infusion System. The subject and predicate devices are similar in design, material composition, components, manufacturing process, intended use and labeling. There are technological differences between the subject and predicate device, however, these differences do not raise new issues of safety and effectiveness. 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.
Gary A. Gulyas
Quality Manager

Signature

12/17/99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2000

Mr. Gary A. Gulyas
Quality Manager
B. Braun Medical, Inc.
1601 Wallace Drive, Suite 150
Carrollton, Texas 75006

Re: K994375
Trade Name: Horizon® Lite
Regulatory Class: II
Product Code: FRN
Dated: December 20, 1999
Received: December 27, 1999

Dear Mr. Gulyas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4690. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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 (if known) K994375

Device Name: Horizon® Lite

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Patricia Cuenoud

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K994375