Premarket Notification 510(k) K042121
Summary of Safety and Effectiveness (p. 1 of 3)

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SIGMA International General Medical Apparatus, LLC.
Spectrum with or without Master Drug Library

510(k) Summary

Submitter Information

Company Name & Address:
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Date Summary Prepared: April 12, 2003

Device Information

Generic Name:
Infusion Pump

Trade or Proprietary Name:
Spectrum with or without Drug Library Work Station

Classification Designation:
Class II, 80FRN Infusion Pump

Device Description Information

The Spectrum with Master Drug Library (device) is an infusion pump having a basic description as identified in Title 21 CFR, Part 880, Section 5725. The Spectrum infusion pump consists of electronic circuitry and mechanical mechanisms that are integrated into a lightweight plastic enclosure. The electrical and mechanical operations are software controlled using discrete microcontroller and processor technology. The motor control / feedback pumping mechanism are of the linear peristaltic design using inlet and exit valves for occlusion control. Infusion therapy fluids and selected intravenous (IV) sets are supplied by the device user. The Spectrum infusion pump is specifically manufactured and calibrated for the application of standard gravity infusion sets of a manufacturer's brand, as indicated by the Spectrum's labeling. The IV set is loaded into

the Spectrum infusion pump. After acceptance of program parameters, the pump is started and fluid is propelled by the rhythmic action of the pumping mechanism against the outside surface of the IV tubing. The pump is controlled to create smooth fluid dynamics, precision volumetric accuracy, and uniformity of flow rate profile. The Spectrum infusion pump is small in comparison to the traditional "Large Volume" infusions pumps currently on the market. However, it is designed to be used in a healthcare facility in an IV pole mounted configuration or carried by the user in an ambulatory manner.

The Master Drug Library (MDL) capability is a software package that allows the generation and management of a patented downloadable drug library into to a target infusion pump. The library may be loaded directly into the infusion pump or uploaded into another computer, Personal Assistants (PDA's), or other transfer apparatus (I.e. "smart" C-pen) for wired or wireless communication to the infusion pump. The MDL software reduces the risk of medication errors by providing programmed delivery profiles and limits for a corresponding drug that is intend for a specific use classification. The MDL software will operate on a popular software systems platform (I.e. Windows) and have the capability (using external peripherals) of printing text / barcode labels that may be used to label and identify drug therapy bags and or patient identification labels. Through the application of the C-pen equipment, scanned patient and IV prescription information can be downloaded into the Spectrum infusion pump. The Spectrum infusion pump has the capability of communicating with a hospital information management system. The Spectrum infusion pump uses coded passwords and redundancy checks to mitigate the acceptance of improper information.

Predicate Device Information

The Spectrum with Master Drug Library is considered to be substantially equivalent (as defined by U.S. FDA regulatory information) to other infusion pumps with software managing systems. The safety and effectiveness related to the predicate devices is comparable to the Spectrum with Master Drug Library. Examples of devices within the same regulatory classification as the Spectrum with Master Drug Library are identified as follows:

Premarket Notification, 510(k) Number	**Device Name**	**Applicant**
K030459	Medley™ System with Medication Management System	ALARIS Medical Systems, Inc.
K011975	Horizon Outlook™ with DoseCom™	B. Braun Medical Inc.

The Spectrum infusion pump may also be used without the Master Drug Library. Predicate devices within the same regulatory classification as the Spectrum are identified as follows:

510(k) Summary (continuation)

Premarket Notification, 510(k) Number	Device Name	Applicant
K950766	SIGMA Model 8000 and 8002 Infusion Pumps	SIGMA International General Medical Apparatus, LLC.
K002211	Colleague® CX Volumetric Infusion Pump	Baxter Healthcare Corporation

Intended Use information for Subject Device

The Spectrum infusion pump is intended to be used for the controlled administration of intravenous fluids. These fluids may include blood, blood products or mixtures of pharmaceutical drugs for required patient therapy. The spectrum is used in conjunction with legally marked intravenous administration sets and medications provided by the user. The Master Drug Library is a software package that will add additional features to the Spectrum infusion pump. The Master Drug Library will permit electronic communications with the Spectrum pump and other external peripheral devices. The intended use of the Spectrum pump includes common drug error prevention, through the stand alone settings features of the pump. This includes drug parameter limits and associated drug name identification. With the Master Drug Library, the intended use is to reduce user errors associated with drug selection, drug dose rates, drug dose concentrations, and patient identification associated with the prescribed drug.

Technological Characteristic Information

The technological characteristics of the Spectrum infusion pump are similar in many respects to the predicate devices. The Spectrum and predicated devices share mechanical and electrical assembly design complexity similarities. Their respective designs contain "state-of-the-art" printed circuit board layout system, proven reliable corrosion resistant pumping mechanisms and microcomputer software control intelligence. The functional characteristics including the user interface, alarm sensing systems, and display technology are of similar technological form. The Master Drug Library features and communication interaction with the Spectrum or other peripherals is also technologically similar in nature to the predicate devices. The technological characteristics of the Spectrum and Spectrum with Master Drug Library are substantially equivalent to the predicate device for intended use. Technological differences between the Spectrum and Spectrum with Master Drug Library do not raise new issues of safety and effectiveness.

Non-Clinical Performance Data Information

The determination of substantial equivalency is also based on non-clinical performance data. The testing conducted on the Spectrum infusion pump was in accordance with recognized performance standards for infusion pumps. In addition, non-clinical testing based on the validation of design requirements has been conducted and is provided as support data for this 510(k) submission. The performance data indicate that the Spectrum and Spectrum with Master Drug Library meets specification requirements and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2004

SIGMA International General Medical Apparatus, LLC
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
70 Codman Hill Road
Boxborough, Massachusetts 01779

Re: K042121
Trade/Device Name: Spectrum and Spectrum with Master Drug Library
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: August 18, 2004
Received: August 19, 2004

Dear Mr. Reuber:

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 Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K042121

Device Name: Spectrum, Spectrum with Master Drug Library

Indications for Use

The Spectrum and Spectrum with Master Drug Library is intended to be used for the controlled administration of intravenous fluids. These fluids may include pharmaceutical drugs, blood, blood products and mixtures of required patient therapy. The intended routes of administration consist of the following clinically acceptable routes: intravenous, arterial, subcutaneous, intrathecal, epidural or irrigation of fluid space. The spectrum is intended to be used in conjunction with legally marketed intravenous administration sets and medications provided by the user.

The Spectrum and Spectrum with Master Drug Library is suitable for many user facility applications such as but not limited to hospitals, outpatient care areas, homecare and ambulatory care services.

The Spectrum and Spectrum with Master Drug Library is intended to reduce operator interaction through automated programming thereby helping to reduce errors associated with complex device programming. Parameter programming requires trained healthcare professional confirmation of limits and drug therapy to physician's directive.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

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