JUL 19 2007 K071735

510(k) SUMMARY

Submitters Name: Michael James, Director of Quality
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Contact Person: Same as submitter.
Facility Registration Number: 3005203102
Date Summary Prepared: May 1, 2007

IDENTIFICATION OF MODIFIED DEVICE

Trade Name: Disposable Infusion Pump Kit
Common Name: Disposable Infusion Pump Kit
Panel: General Hospital

Classification Name and Reference:

Pump
Pump, Infusion, Elastomeric, External (21 CFR 880.5725)
Device Classification for the subject and/or predicate devices: Class II
Device Panel Code: 80
Device Product Code: MEB

Catheter Needle/Introducer
Catheter, Accessories (21 CFR 878.4200)
Device Classification for the predicate devices: Class I Exempt
Device Panel Code: 79
Device Product Code: KGZ

Infusion Catheter
Catheter, Conduction, Anesthetic (21 CFR 868.5120)
Device Classification for the subject and/or predicate devices: Class II
Device Panel Code: 73
Device Product Code: BSO

IDENTIFICATION OF THE LEGALLY MARKETED DEVICE

Trade Name: Disposable Infusion Pump Kit
Common Name: Disposable Infusion Pump Kit
510(k) Number: K051474
Panel: General Hospital

Classification Name and Reference:

Pump
Pump, Infusion, Elastomeric, External (21 CFR 880.5725)
Device Classification for the subject and/or predicate devices: Class II
Device Panel Code: 80
Device Product Code: MEB

Catheter Needle/Introducer
Catheter, Accessories (21 CFR 878.4200)
Device Classification for the predicate devices: Class I Exempt
Device Panel Code: 79
Device Product Code: KGZ

Infusion Catheter
Catheter, Conduction, Anesthetic (21 CFR 868.5120)
Device Classification for the subject and/or predicate devices: Class II
Device Panel Code: 73
Device Product Code: BSO

DESCRIPTION OF THE DEVICE

Infusion of liquids into a patient in the general hospital setting as well as at home is frequently required in medical treatment. For example, in orthopedics a disposable device is often indicated after outpatient arthroscopic surgery in order to infuse local anesthetics for several days following the patient's return home. The infusion catheter is usually removed when the patient returns to the physician's office for a follow-up visit.

The Symbios Disposable Infusion Pump Kit is a convenience kit that includes the components necessary to provide temporary infusion of a liquid into a patient. The components of the system are an elastomeric pump, a catheter needle/introducer, an infusion catheter and accessories. The pump is a disposable, self-contained, infusion system utilizing an inflatable elastomeric reservoir to mechanically pressurize a fluid and drive it through tubing to a small restrictor to provide infusion at a pre-set rate.

The device is provided empty and no specific drug references are made in the labeling. The device is not intended for delivery of blood, blood products, lipids or fat emulsions.

INTENDED USE OF THE DEVICE

(Same for both the modified and unmodified predicate device)

The Symbios Disposable Infusion Pump Kit is a disposable, self-contained infusion system utilizing an inflatable elastomeric reservoir to mechanically provide percutaneous infusion of prescribed solutions at a pre-set rate for post-operative pain management.

NEW DEVICE IN COMPARISON WITH PREDICATE DEVICE

Minor modifications have been made to the Disposable Infusion Pump Kit cleared in 510(k) Number K051474.

1. The fill volume has been increased from 100 ml to 150 ml. The design (dimensions, materials, assembly methods) of the pump remains unchanged. Note - The design of the predicate device was capable of a 150 ml fill volume, but only tested and verified to 100 ml. Diagrams of the modified and predicate pump assemblies are shown in Attachment 2.
2. The catheter needle/introducer included in the kit has been extended to include needle/introducers that are as long as 10 inches in length, and up to 14 gauge (GA) in diameter. The increased size is needed for patients with larger bodies. The needle material remains stainless steel, while the introducer catheter material could be either Teflon or polyethylene.

Pump

	Modified Device	Predicate Device
510(k) Number	New	K051474
Manufacturer	Symbios Medical Products, LLC	Symbios Medical Products, LLC
Type	Elastomeric Pump	Elastomeric Pump
Fluid Reservoir	Sold empty and capable of being filled via a fill port	Sold empty and capable of being filled via a fill port
Reservoir Material	Synthetic rubber, latex-free elastomeric membrane	Synthetic rubber, latex-free elastomeric membrane
Pressure Source	Strain energy of elastomeric membrane	Strain energy of elastomeric membrane
Fill Volume	150 ml	100 ml
Flow Rate	2.0 ml/hr	2.0 ml/hr
Flow Profile	Continuous	Continuous
Accuracy	± 15%	± 15%
Power Requirement	None	None
Tubing	Integrated	Integrated
Tubing Material	PVC	PVC
Flow Control	Consistent flow rate throughout the entire course of therapy is achieved by orifice size (no change)	Consistent flow rate throughout the entire course of therapy is achieved by orifice size
Safety Features	Fixed Flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary. (no change)	Fixed Flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.

Catheter Needle/Introducer

	Modified Device	Predicate Device
FDA Status	Exempt (878.4200)	Exempt (878.4200)
Sponsor/Manufacturer	Martech	Martech
Material – Needle	Stainless Steel	Stainless steel
Material – Introducer Catheter	Teflon or Polyethylene	Teflon
Needle Size	Up to 14 GA	16 GA
Needle Length	Up to 10"	2.75"

STERILITY INFORMATION

EtO sterilization with the following parameters:

Sterility Assurance Level: 10^{-6}

Sterility Validation Method: ANSI/AMMI/ISO 11135-1994

The maximum levels of residuals allowable:

Ethylene Oxide (EtO)	<25ppm
Ethylene Chlorohydrin	<25ppm
Ethylene Glycol	<250ppm

Packaging Description: The kit will be packaged in a sealed Tyvek/polymylar pouch, and then placed with the Directions for Use inside another larger sealed Tyvek/polymylar pouch.

Labeling: All packages will display a statement that the device has been sterilized by EtO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2007

Mr. Michael James
Director of Quality
Symbios Medical Products, LLC
7301 Georgetown Road, Suite 150
Indianapolis, Indiana 46268

Re: K071735
Trade/Device Name: Disposable Infusion Pump Kit
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump, Introduction/drainage Catheter, Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: MEB, KGZ, BSO
Dated: June 25, 2007
Received: June 27, 2007

Dear Mr. James:

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 (240) 276-0120. 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/industry/support/index.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

ATTACHMENT 1

Indications for Use

510(k) Number: K071735

Device Name: Disposable Infusion Pump Kit

Indications for Use:

The Disposable Infusion Pump is a disposable, self-contained infusion system utilizing an inflatable elastomeric reservoir to mechanically provide percutaneous infusion of prescribed solutions at a preset rate for post-operative pain management.

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

510(k) Number: K071735