K051474

JUL 1 - 2005

Exhibit 6
Summary of Safety and Effectiveness

Trade Name: Disposable Infusion Pump Kit

Common Name: Disposable Infusion Pump Kit

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, Intravascular, short term (21 CFR 880.5200)
- Device Classification for the subject and/or predicate devices: Class II
- Device Panel Code: 80
- Device Product Code: FOZ

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

Device description:

Infusion of liquids in to 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 topical 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 a bandage. 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:

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 - 2005

Mr. Jeffery J. Alholm
CEO
Symbios Medical Products, LLC
6131 West 80th Street
Indianapolis, Indiana 46278

Re: K051474
Trade/Device Name: Disposable Infusion Pump Kit
Regulation Number: 21 CFR 880.5725, 880.5200, 868.5120
Regulation Name: Infusion pump, Intravascular catheter, Anesthesia conduction catheter
Regulatory Class: II
Product Code: MEB, KGZ, BSO
Dated: June 2, 2005
Received: June 7, 2005

Dear Mr. Alholm:

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.

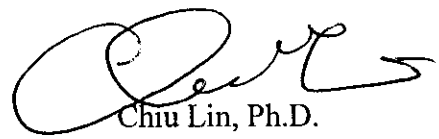
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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

Indications for Use

510(k) Number (if known): K051474

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: K051474