K05 3226

JAN 3 1 2006

Summary of Safety and Effectiveness

Submitter:

Zimmer Orthopaedic Surgical Products
200 West Ohio Avenue
P.O. Box 10
Dover, Ohio 44622

Contact Person:

Cindy J. Dickey
Regulatory Compliance Manager
Telephone: (330) 364-9493
Fax: (330) 364-9490

Date:

November 15, 2005

Trade Name:

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 2,4,6 ml/hr and 2.5 inch fenestrated catheter

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 2,4,6 ml/hr with PCM and 2.5 inch fenestrated catheter

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 3,5,8 ml/hr and 2.5 inch fenestrated catheter

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 3,5,8 ml/hr with PCM and 2.5 inch fenestrated catheter

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 2,4,6 ml/hr and 5.0 inch fenestrated catheter

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 2,4,6 ml/hr with PCM and 5.0 inch fenestrated catheter

053226

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 3,5,8 ml/hr and 5.0 inch fenestrated catheter

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 3,5,8 ml/hr with PCM and 5.0 inch fenestrated catheter

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 2,4,6 ml/h with Flow Splitter Kit

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 3,5,8 ml/h with Flow Splitter Kit

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 2,4,6 ml/h with PCM and Flow Splitter Kit

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 3,5,8 ml/h with PCM and Flow Splitter Kit

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 2,4,6 ml/h with Flow Splitter Kit and 2.5 inch fenestrated catheters

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 3,5,8 ml/h with Flow Splitter Kit and 2.5 inch fenestrated catheters

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 2,4,6 ml/h with PCM and Flow Splitter Kit and 2.5 inch fenestrated catheters

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 3,5,8 ml/h with PCM and Flow Splitter Kit and 2.5 inch fenestrated catheters

K053296

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 2,4,6 ml/h with Flow Splitter Kit and 5.0 inch fenestrated catheters

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 3,5,8 ml/h with Flow Splitter Kit and 5.0 inch fenestrated catheters

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 2,4,6 ml/h with PCM and Flow Splitter Kit and 5.0 inch fenestrated catheters

ZIMMER AMBULATORY PUMP Pain Management System, MULTIRATE INFUSOR 3,5,8 ml/h with PCM and Flow Splitter Kit and 5.0 inch fenestrated catheters

ZIMMER AMBULATORY PUMP Flow Splitter Kit

ZIMMER AMBULATORY PUMP 2.5 inch Fenestrated Catheter Kit

ZIMMER AMBULATORY PUMP 5.0 inch Fenestrated Catheter Kit

Common Name:

Pump, Infusion, Elastomeric

Classification Name and Reference:

Pump, Infusion, Elastomeric
21 CFR § 880.5725

Predicate Devices:

Zimmer Ambulatory Pump Kit Pain Management System manufactured by Zimmer Orthopaedic Surgical Products, K050433, cleared April 13, 2005.

Zimmer Ambulatory Pump Kit Pain Management System with PCM, manufactured by Zimmer Orthopaedic Surgical Products, K052171, cleared September 27, 2005.

K05-3296

Accufuser; Accufuser Plus; Standard Procedure Kit, manufactured by McKinley, Inc., K033039, cleared October 7, 2003.

Accufuser; Accufuser Plus; Standard Procedure Kit, manufactured by McKinley, Inc., K023098, cleared December 9, 2002.

Device Description:

Accessory kits:
The *Zimmer* Ambulatory Pump Pain Management System Accessory Kits are convenience kits that are comprised of legally marketed devices. The devices are purchased non-sterile and subsequently packaged into double-pouched kits by *Zimmer*. Once packaged, the kit will be sent to a contract sterilizer for irradiation sterilization. The proposed accessory kit does not change the intended use of the legally marketed devices which comprise the kit.

Pump kits with included accessories:
The Zimmer Ambulatory Pump Pain Management System Kits are comprised of approved Zimmer systems with the addition of the convenience kits, comprised of legally marketed devices. The devices are purchased non-sterile and subsequently packaged into tyvek-sealed trays sealed by *Zimmer*. Once packaged, the System will be sent to a contract sterilizer for irradiation sterilization. The proposed addition of the convenience kit(s) does not change the intended use of the legally marketed devices which comprise the kit.

The *Zimmer* Ambulatory Pump Pain Management System Kits do not raise any new safety and effectiveness concerns when compared to the similar legally marketed devices. The *Zimmer* Ambulatory Pump Pain Management System Kits should therefore be considered substantially equivalent to the existing predicate devices.

Indications for Use:

The Zimmer Pain Management System and Zimmer Pain Management System with Patient Control Module (PCM) are indicated for the slow,

K053226

	continuous or subcutaneous administration of pain medications. It may also include the slow, continuous infusion of pain medications directly into an intraoperative, or subcutaneous site for postoperative pain management or the continuous infusion of a local anesthetic near a nerve for regional anesthesia. The PCM allows for intermittent bolus doses of medication on patient demand. The system is convenient for use by ambulatory patients. It is the responsibility of the healthcare provider to assure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
Comparison to Predicate Device:	The *Zimmer* Ambulatory Pump Pain Management Kit (with and without PCM) and flow splitter wye and fenestrated catheter kits are substantially equivalent to the legally marketed pain management kits, specifically the *Zimmer* Ambulatory Pump Pain Management Systems, McKinley Accufuser; Accufuser Plus, Standard Procedure Kits in that the kits are similar in design, materials, and indications for use.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The devices in this kit have been tested to determine the impact of sterilization as per the guidance document, "Sterilized convenience kits for clinical and surgical use; final guidance for industry," January 7, 2002 was utilized as guidance for this submission. The previously cleared devices have been tested and do meet the applicable sections of the ANSI/AAMI/ ISO 10993-1:1997, "Biological evaluation of Medical Devices."
Clinical Performance and Conclusions:	Clinical data and conclusions were not needed for these kits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2006

Ms. Cindy J. Dickey
Regulatory Compliance Manager
Zimmer Orthopaedic Surgical Products
200 West Ohio Avenue
P.O. Box 10
Dover, Ohio 44622-0010

Re: K053226
Trade/Device Name: Zimmer Ambulatory Pump Pain Management System with Fenestrated Catheter and/or Flow Splitter and the Zimmer Ambulatory Pump Pain Management System with PCM and Fenestrated Catheter and or Flow Splitter.
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: November 15, 2005
Received: November 17, 2005

Dear Ms. Dickey:

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

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): K053226

Device Name:

Zimmer Ambulatory Pump Pain Management System with fenestrated catheter and/or flow splitter and the *Zimmer* Ambulatory Pump Pain Management System with PCM and fenestrated catheter and/or flow splitter. Optional fenestrated catheter kits in various fenestrated lengths and multi-site flow splitter kit are also offered separately.

Indications for Use:

The *Zimmer* Pain Management System and Zimmer Pain Management System with Patient Control Module (PCM) are indicated for the slow, continuous or subcutaneous administration of pain medications. It may also include the slow, continuous infusion of pain medications directly into an intraoperative, or subcutaneous site for postoperative pain management or the continuous infusion of a local anesthetic near a nerve for regional anesthesia. The PCM allows for intermittent bolus doses of medication on patient demand. The system is convenient for use by ambulatory patients. It is the responsibility of the healthcare provider to assure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (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
510(k) K053226