K993972

FEB 7 2000

BIOMET INC

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Proprietary 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

IV Catheter/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 Biomet 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, an IV catheter/introducer and an infusion catheter. 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 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 pre-set rate for post-operative pain management.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Incorporated
Corporate Headquarters
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K993972
Trade Name: Disposable Infusion Pump Kit
Regulatory Class: II
Product Code: MEB
Dated: January 13, 2000
Received: January 20, 2000

Dear Ms. Beres:

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) 594-4692. 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

K993972

510(k) Number (if known): K993972

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 pre-set rate for post-operative pain management.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993972