K011868

SEP - 4 2001

510(k) Summary

Sponsor: Debiotech S.A.

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Original Date prepared: June 13, 2001

Proprietary name: Enteral Exprés Pump Unit
Enteral Exprés Giving Sets

Common name: Enteral Pump
Intravascular Administration Sets

Classification name: LZH - External Enteral Infusion Pump
FPA – Intravascular (IV) Administration Set

Substantial equivalence claimed to:
Sherwood Medical Kangaroo Pump – K945964

Description:

The Enteral Exprés enteral feeding pump system is intended for the programmed delivery of enteral nutrition fluids to the patient. It may be used in hospitals, outpatient, or home healthcare sites on immobilized or ambulatory patients.

The "Enteral Exprés" system offers the following capabilities:

- CONTINUOUS, PROGRESSIVE, and PROGRESSIVE – INTERMITTENT delivery modes to meet different patient needs
- Wide range of programmable delivery rates: from 1 to 999 mL/hr
- One way, snap-in cassette simplifies giving set loading

- Safety features that help prevent tampering with the pump include keypad lock and program lock
- Keypad and display are simple and easy to use, and display provides English or Spanish information
- Battery or AC-powered operation. Battery life monitored by internal battery gauge
- Small, quiet, and lightweight to enhance patient comfort

Intended use:

The Enteral Exprés enteral fluid delivery system is intended to provide delivery of standard enteral nutrition fluids to patients in the hospital and in alternate site care.

Summary of technological characteristics:

The Enteral Exprés pumping mechanism is comprised of a cassette assembly and the pump. The majority of the pumping mechanism is incorporated into the cassette assembly, with the motor and it's controlling electronics and shaft being incorporated in the pump.

The cassette incorporates three rollers and a length of silicone tubing housed in a closed cassette assembly. Loading the cassette onto the motor shaft causes the rollers to expand outward, crushing the tubing against the inside walls of the cassette body and occluding gravity flow through the system. As the motor shaft rotates, the rollers rotate and the crushed portion of the tubing translates across the inner circumference of the cassette body. This results in a rotary peristaltic pumping action. The accuracy of the system is largely determined by the components in the cassette. Of these components, the inner diameter of the tubing is the primary factor in determining the volumetric output per rotation.

Within the pump the motor is directly coupled to the drive shaft through a sprag clutch to prevent reverse rotation. The motor is controlled by the microprocessor and redundant circuitry is used to verify the proper rotation of the shaft. The accuracy of the motor's rotation rate is established by synchronizing the signal from the motor's encoder with a signal generated by a programmable frequency divider. The accuracy of the frequency divider is monitored by an independent microprocessor clock circuit. Microprocessor integrity is, in turn, monitored with self-check routines and watchdog circuitry.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Debiotech S.A.
C/O Mr. Sean Curry
Chief Operating Officer
Certified Software Solutions
16787 Bernardo Center Drive, Suite A-1
San Diego, California 92128-2504

Re: K011868
Trade/Device Name: Enteral Expres Pump Unit, Enteral Expres Giving Sets
Regulation Number: 880.5725
Regulatory Class: II
Product Code: LZH
Dated: June 13, 2001
Received: June 14, 2001

Dear Mr. Curry:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4618. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011868

Device Name:

Indications for Use:

The Enteral Exprés enteral fluid delivery system is intended to provide delivery of standard enteral nutrition fluids to patients in the hospital and in alternate site care.

(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)

Vale Hilland for Pat Cricenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011868