DELPHI
Medical Systems
5725 Delphi Drive Troy, MI 48098-2815 USA

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Section V 510(k) Summary (As required by section 807.92(c))

Submitter: Delphi Medical Systems
5725 Delphi Drive
Troy MI 48098

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FDA CDRH DMC

NOV 27 2009

Received

Date Prepared: July 2009

DEVICE NAME AND CLASSIFICATIONS

Type of Submission: Traditional 510(k)

Proprietary Name: Delphi Infusion Pump / Delphi Infusion Sets
Model IV-01000 / Model IV-02XXXX (X = 0-9)

Common Name: Infusion Pump / Infusion Set

Classification Name: Pump, Infusion / Set, Administration, Intravascular

Product Code: FRN / FPA

Medical Specialty / Panel: General Hospital

Device Classification: Class II

Regulation Number: 21 CFR 868.5440 / 21 CFR 880.5440

Predicate Device: Delphi Medical Systems, IVantage Infusion Pump, 510(k) # K953896*
Sigma International, Spectrum and Spectrum with Master Drug Library, 510(k) # K042121

Indications For Use:

The Delphi Infusion Pump is intended for use in the controlled delivery of epidural and IV solutions.

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Intended Use:

The pump shall deliver medications in a safe and accurate manner over a broad range of flow rates and parameters. The pump shall be compatible with lipids, blood and blood products, saline, Total Parenteral Nutrition (TPN), or any IV medication. This pump is intended to operate in a clinically appropriate environment under the supervision of a licensed health care professional

Device Description:

The Delphi Infusion Pump is a large volume infusion pump customizable to meet the specific needs of multiple care areas and deliver a wide range of therapies in a safe and effective manner. For each area of care, clinically appropriate alarms, alerts, and performance specifications can be established. With the available Safety Suite, the pharmacy can define default and safe operating ranges for all drugs being infused. There are four basic infusion modes available plus epidural delivery.

Continuous Mode

These are infusions which deliver a defined volume to be infused (VTBI) at a constant flow rate. Optionally, a weight based approach can be used to enter the dose rate. The ability to infuse secondary infusions as well as keep vein open (KVO) settings are available. After infusion has begun, infusion rate can be changed temporarily using Titrate or for the duration of the infusion using Rate Change.

Intermittent Mode (Dose Mode and Multi-Step Mode)

This infusion mode allows the user to either repeat the same dose a programmable number of times (Dose Mode) or to program a series of doses at varying rates and durations (Multi-Step Mode).

Total Parenteral Nutrition (TPN) Mode

This infusion mode allows the user to ramp the delivery rate up at the beginning of an intravenous nutrition delivery and ramp down the delivery rate at the end.

Patient Controlled Analgesia (PCA) Mode

This infusion mode allows the patient to initiate doses of medication on an as-needed basis within preset limits. The clinician is given the ability to program a loading dose, basal rate, and controlled bolus doses.

Epidural Delivery

Allows access to Continuous, PCA, and Intermittent Epidural Modes and is indicated by a yellow background screen.

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The Delphi Infusion Pump uses a rotary peristaltic pumping mechanism with dedicated disposable administration sets. Each administration set includes a precision-molded cassette designed for fast, safe, and secure single-handed pump loading. A safety slider switch on the cassette, along with a roller clamp, provides redundant free-flow protection when the tubing is unloaded. The user interface was designed using extensive input from clinical and human factors experts to offer a unique combination of a large touch screen display and a keypad for alpha-numeric data entries. The pump is designed for use on AC power with battery backup during power failure and is available during patient ambulation and transport. The portable light weight single-channel design allows for a dedicated display ("one screen, one drug") and improved utilization and increased flexibility in device placement.

Delphi Administration Sets are available in a variety of configurations containing components such as needleless Y-Sites, filters, drip chambers, PE-lined tubing, etc and a common cassette to interface with the Delphi Infusion Pump.

The Delphi Infusion pump will include the option of a Master Drug Library which provides customers the ability to set defined dose limits specific to their individual formulary. Dose limits may be attached to specific care areas and instances where dose limits are exceeded can be recorded. Biomedical setting options include the ability to set clinically appropriate alarms, alerts and performance specifications.

Technological Characteristics:

The Delphi Infusion Pump uses a 3-roller rotary peristaltic pump to deliver fluids from a container to a patient. As the motor shaft rotates, the rollers on the pump rotate and the compressed portion of the tubing translates across the inner circumference of the cassette housing. This results in a rotary peristaltic pumping action. At a minimum, one of the rollers is always in contact with the infusion set to prevent free-flow during infusion and when not infusing.

The pump mechanism contains both an up/down stream occlusion sensors and an ultrasonic sensor for air detection. The pump can be programmed to detect occlusion and air sensitivity at high, low, and auto-sensing. The roller mechanism uses a 3-phase brushless motor with hall sensors and a flag sensor for redundant sensing of motor rotation. The Delphi Infusion Pump detects a variety of system alarms to monitor for proper operation of the device, Cassette detection, Occlusion, and Air-in-Line alarms.

The pump uses a large color touch screen and alphanumeric keypad to view operational status and program infusion. Each keypress is identified by an auditory feedback to the user.

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The infusion sets contain a cassette that is custom designed to interface with the Delphi Infusion Pump and has an integrated free-flow protection that occludes the tubing.

The technological characteristics of the Delphi Infusion Pump are substantially equivalent to the predicate device noted in the submission and these technologies are well established for Delphi Infusion Pumps.

Substantial Equivalence

Both predicate device and Delphi Infusion Pump are substantially equivalent in performance and are intended to be used for the same purpose. The two products are different from each other only by User Interface, battery duration, size, and weight. Larger user interface and custom software reduces entry error by a clinician. Also, the Delphi Infusion Pump contains more alarms and indicators for the user than the predicate device. The Delphi Infusion Pump is larger in size than the predicate device but is still able to be used in a typical clinical environment.

Performance Requirement

Bench performance testing has also demonstrated that the Delphi Infusion Pump is substantially equivalent in performance as the predicate device in flow accuracy and in construction when compared using performance standards for infusion pumps.

Furthermore, the Delphi Infusion Pump will also be tested for safety, EMI/EMC, and will bear a safety marked from a Nationally Recognized Testing Laboratory, which will be substantially equivalent to the safety, EMI/EMC testing, and safety mark on the predicate device.

Conclusion:

The Delphi Infusion Pump is substantially equivalent in function, technological characteristics, and intended use to other devices currently in commercial distribution, namely the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC - 9 2009

Delphi Medical Systems
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriter Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K093332
Trade/Device Name: Delphi Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: November 27, 2009
Received: November 27, 2009

Dear Mr. Devine:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section IV: Indications for Use Statement

Applicant: Delphi Medical Systems

510(k) Number: K993332

Device Name: Delphi Infusion Pump

Indications for Use:

The Delphi Infusion Pump is intended for use in the controlled delivery of epidural and IV solutions.

Prescription Use Only: X Over-the-Counter Use: _____

(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

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