AUG 1 3 2002

K020655

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Deltec Cozmo™ Insulin Infusion Pump (Model 1700) and Accessories

June 3, 2002

I. GENERAL INFORMATION

Applicant's Name and Address:	Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Lisa J. Stone Manager, Regulatory Affairs
Common/Usual Name:	Insulin Infusion Pump and Accessories
Proprietary Name:	Deltec Cozmo™ Insulin Infusion Pump (Model 1700) and Accessories
Equivalence Device Comparison:	MiniMed Model 508 Insulin Pump, MiniMed 3.0 ml Reservoir, Deltec CADD-Diplomat® System, and MiniMed Com-Station™ Communication System

II. DEVICE DESCRIPTION

The Deltec Cozmo™ Insulin Infusion Pump is a small, ambulatory, battery-powered, microprocessor controlled, external insulin syringe pump. Key features of the pump include: backlit liquid crystal display (LCD), 4-key keypad, separate audio bolus button, AAA-battery power source, waterproof, audible alarm option, vibratory alarm option, real time clock, belt-clip and interface, various basal and bolus delivery rates, stored memory, PC-downloading and programming capability, IR windows, 3-ml cartridge, cartridge cap and child-proof cartridge cap.

The Deltec Cozmo™ 3-ml Cartridge is a syringe style reservoir and is a proprietary design for use specifically with the Deltec Cozmo™ Insulin Infusion Pump. It is not compatible with other pumps. The 3-ml Cartridge is made of three separate pieces: barrel, plunger and rod. The barrel has an integral luer fitting on one end, volume markings, and a raised ring at the opposite end of the luer fitting that acts as a stop for the plunger. The plunger is conical in shape with a double o-ring seal design. The plunger and rod are detachable with a snap-fit design. The rod is removed from the plunger prior to cartridge insertion into the pump.

The Deltec Cozmo™ Treatment Assistant™ PC Communications System is a software program, which allows communications between a personal computer (PC) and an infusion pump. It allows for downloading of information from the pump to a PC and for programming of the pump via a PC. The "connection" between the pump

and the PC is via infra-red (IR) windows on the back of the pump and the computer's IR port. A standard off-the-shelf IR cable connector for the PC may also be used if the user's computer does not have an integral IR port.

III. INTENDED USE OF THE DEVICE

The Deltec Cozmo™ Insulin Infusion Pump (Model 1700) is a syringe infusion pump designed for Continuous Subcutaneous Insulin Infusion (CSII) for the control of diabetes.

The Deltec Cozmo™ 3-ml Cartridge is designed for use with the Deltec Cozmo™ Insulin Pump for Continuous Subcutaneous Insulin Infusion (CSII).

The Deltec Cozmo™ Treatment Assistant™ PC Communications System is designed for use with the Deltec Cozmo™ Insulin Infusion Pump as a tool in optimizing diabetes management. It allows communications between the pump and a computer for accessing data stored in pump memory, and programming of the pump.

IV. DEVICE COMPARISON

The Deltec Cozmo™ Insulin Infusion Pump is similar in design, function, and intended use to the MiniMed Model 508 Insulin Pump (K990801). The pumps are small, ambulatory, battery-powered, microprocessor controlled, external insulin syringe pump delivery systems. Each device is indicated for the delivery of insulin and includes the following features: backlit liquid crystal display (LCD), 4-key keypad, audible alarm option, vibratory alarm option, real time clock, belt-clip and interface, various basal and bolus delivery rates, stored memory, PC-downloading capability, IR windows, and 3-ml medication cartridge.

The Deltec Cozmo™ 3-ml Cartridge is similar in design, function, and intended use to the MiniMed 3-ml Reservoir (K991936). Each device is a syringe style reservoir with a capacity of 3 ml. They are made of the same materials and both are provided with a 22-gauge needle. Each device is indicated for use in the infusion of insulin with an external infusion pump.

The Deltec Cozmo™ Treatment Assistant™ PC Communications System is similar in design, function, and intended use to the Deltec CADD-Diplomat® System (K973917). The products allow communications between a personal computer (PC) and an infusion pump. The software programs allow for downloading of information from the pump to a PC and for programming of the pump via a PC. The Deltec Cozmo™ Treatment Assistant™ PC Communications System is also similar to the MiniMed Com-Station™ Communication System (K993012), which uses IR communication.

V. SUMMARY OF STUDIES

A. Functional Testing

Test plans associated with software validation, verification of software controlled programming functions, and software related to proper pump operation were certified for the Deltec Cozmo™ Insulin Infusion Pump and the Deltec Cozmo™ Treatment Assistant™ Communications System.

In-vitro testing and biocompatibility testing was performed on the Deltec Cozmo™ 3-ml Cartridge.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the use of the Deltec Cozmo™ Insulin Infusion Pump and Accessories.

C. Conclusions Drawn from Studies

Based upon the information provided above, the Deltec Cozmo™ Insulin Infusion Pump and Accessories are substantially equivalent to other commercially available devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

Ms. Lisa Stone
Managing, Regulatory Affairs
Deltec, Incorporated
1265 Grey Fox Road
Saint Paul, Minnesota 55112

Re: K020655
Trade/Device Name: Deltec Cozmo™ Insulin Infusion Pump (Model 1700), Deltec Cozmo™ 3-ml Cartridge, and Deltec Cozmo™ Treatment Assistant™ PC Communications System
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: June 3, 2002
Received: June 4, 2002

Dear Ms. Stone

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 and additionally 21 CFR Part 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 Part 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,

for

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

Enclosure

510(k) Number (if known): K020655

Device Name: Deltec Cozmo™ Insulin Infusion Pump (Model 1700), Deltec Cozmo™ 3-ml Cartridge, and Deltec Cozmo™ Treatment Assistant™ PC Communications System

Indications for Use:

"The Deltec Cozmo™ Insulin Infusion Pump (Model 1700) is a syringe infusion pump designed for Continuous Subcutaneous Insulin Infusion (CSII) for the control of diabetes."

"The Deltec Cozmo™ 3-ml Cartridge is designed for use with the Deltec Cozmo™ Insulin Infusion Pump for Continuous Subcutaneous Insulin Infusion (CSII).

"The Deltec Cozmo™ Treatment Assistant™ PC Communications System is designed for use with Deltec Cozmo™ Insulin Infusion Pump as a tool in optimizing diabetes management. It allows communications between the pump and a computer for accessing data stored in pump memory, and programming the pump."

(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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K020655