MAY 27 2004

K031738

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Deltec Cozmo™ Insulin Infusion Pump with CoZmonitor™ Glucose Monitor

April 9, 2004

I. GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical MD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	David H. Short Director Regulatory and Clinical Affairs
Common/Usual Name:	Insulin Infusion Pump and Glucose Monitor
Proprietary Name:	Deltec Cozmo® Insulin Infusion Pump with CoZmonitor™ Glucose Monitor
Equivalence Device Comparison:	Deltec Cozmo® Insulin Infusion Pump and TheraSense FreeStyle Tracker™ Diabetes Management System

II. DEVICE DESCRIPTION

A CoZmonitor™ Glucose Monitor is a modified FreeStyle Tracker™ meter module designed to be coupled with the Deltec Cozmo® Insulin Pump. The Deltec Cozmo® Insulin Infusion Pump with CoZmonitor™ Glucose Monitor is lightweight and easy to use. Users follow their usual practice of blood sampling. The FreeStyle™ test strip is inserted into the CoZmonitor™ Glucose Monitor, which is attached to the Deltec Cozmo® Insulin Pump.

The CoZmonitor™ Glucose Monitor will automatically transfer the blood glucose information to the Deltec Cozmo® Pump through an infrared port. If the user's blood glucose level is higher than normal, he or she can go directly to the bolus menu of the pump to correct it without having to manually re-enter the blood glucose value, ensuring more consistent insulin delivery.

In addition, blood glucose results are combined with insulin delivery data and stored in the Deltec Cozmo® Pump's history log to provide a complete picture of the user's diabetes management, allowing them to be more proactive in their insulin decisions. The system's central data storage capabilities also allow users to go through fewer steps and therapy calculations – reducing the risk of data or transcription errors.

III. INTENDED USE OF THE DEVICE

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

The Deltec CoZmonitor™ Blood Glucose Monitor is available as an accessory to be used solely with the Deltec Cozmo® Insulin Pump. Because the monitor is powered by FreeStyle™, blood sampling can be performed using the finger, forearm, upper arm, thigh, calf or hand. All testing is performed outside of the body (in other words, *in-vitro* diagnostic use only). Use only with FreeStyle™ Test Strip and FreeStyle™ Control Solution, as other products can give inaccurate results.

The Deltec CoZmonitor™ Blood Glucose Monitoring System is designed to be used only with the Deltec Cozmo® Insulin Pump to help you and your healthcare provider monitor your diabetes management program. When used properly, the monitor provides a quantitative measurement of glucose (or sugar) in whole blood. Because the monitor is powered by FreeStyle™, blood sampling can be performed using the finger, forearm, upper arm, thigh, calf or hand. All testing is performed outside of the body (in other words, *in-vitro* diagnostic use only). Use only with FreeStyle™ Test Strip and FreeStyle™ Control Solution, as other products can give inaccurate results.

IV. DEVICE COMPARISON

The Deltec Cozmo® Insulin Pump is very similar to the currently distributed pump, with the exception of updated software to allow for its use with the CoZmonitor™ Glucose Monitor.

The CoZmonitor™ Glucose Monitor is a modified FreeStyle Tracker™ meter module designed to be coupled with the Deltec Cozmo® Insulin Pump.

The FreeStyle Tracker™ meter module was modified to include the mechanical connections to allow for the connection to a Deltec Cozmo® Insulin Pump along with designing the module to fit on the back of the pump, updated software to allow for use with the pump, infrared ports to allow for communications with the pump, and the use of a CR2032 battery

V. SUMMARY OF STUDIES

A. Functional Testing

Software validation, verification of software controlled programming functions, and software related to proper pump operation were completed for the Deltec Cozmo® Insulin Pump with CoZmonitor™ Glucose Monitor.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the Deltec Cozmo® Insulin Pump with CoZmonitor™ Glucose Monitor due to their similarity in design and function to the current Deltec Cozmo™ Insulin Pump and TheraSense FreeStyle Tracker™ monitor.

Usability studies of the Deltec CoZmonitor™ Blood Glucose Monitoring System were conducted with 57 participants (23 females and 32 males) ranging in age from 9 years to 76 years. Two participants did not provide their age. All participants were Deltec Cozmo® Insulin Pump users

and ranged from 1 month to >12 months. Five participants did not provide the length of time they had used the Deltec Cozmo® Insulin Pump.

Participants were asked to obtain their blood glucose reading and 57 of 57 participants were able to successfully obtain their blood glucose reading within two attempts, 55 of 57 participants successfully obtain blood glucose readings with their first attempt.

Participants were also provided three control samples with low, middle, and high glucose concentrations and were asked to obtain glucose readings from each sample and 52 of 57 participants were able to obtain correct blood glucose readings using the low, middle and high control samples. Of the 5 participants that did not obtain correct glucose readings, 1 participant obtained an out of range reading for the high control on test and retest; one participant obtained an out of range reading for a middle control, but did not retest; two participants did not sample 1 of the 3 control samples, but were able to obtain correct readings for the other two control samples.

Participants were asked to attach the CoZmonitor™ Glucose Monitor to the Deltec Cozmo® Insulin Pump and 55 of 57 participants indicated the CoZmonitor™ Glucose Monitor was easy to attach to the Deltec Cozmo® Insulin Pump. 55 of 57 participants indicated the CoZmonitor™ Glucose Monitor was easy to use. 55 of 57 participants indicated the CoZmonitor™ Glucose Monitor System was easy for them to know what to do based on the messages displayed on the Deltec Cozmo® Insulin Pump screen. 56 of 57 participants indicated that it was easy for them to select the appropriate choice from Deltec Cozmo® Insulin Pump menu options to bring their blood glucose reading back on target. 56 of 57 participants indicated that they successfully used the CoZmonitor™ Glucose Monitor.

C. Conclusion Drawn from the Studies

Based upon the information provided above, the Deltec Cozmo® Insulin Pump with CoZmonitor™ Glucose Monitor is 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

MAY 27 2004

Mr. David H. Short
Director Regulatory and Clinical Affairs
Smiths Medical MD, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K031738
Trade/Device Name: Deltec Cozmo® Insulin Pump with CoZmonitor™ Glucose Monitor
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: March 16, 2004
Received: March 17, 2004

Dear Mr. Short:

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), please contact the Office of Compliance at (301) 594-4618. 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/dsma/dsmamain.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): K031738

Device Name: Deltec Cozmo® Insulin Pump with CoZmonitor™ Glucose Monitor

Indications for Use:

Deltec Cozmo® Insulin Pump

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

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

Indications for Use:

CoZmonitor™ Glucose Monitor

The Deltec CoZmonitor™ Blood Glucose Monitor is available as an accessory to be used solely with the Deltec Cozmo® Insulin Pump. Because the monitor is powered by FreeStyle™, blood sampling can be performed using the finger, forearm, upper arm, thigh, calf or hand. All testing is performed outside of the body (in other words, *in-vitro* diagnostic use only). Use only with FreeStyle™ Test Strip and FreeStyle™ Control Solution, as other products can give inaccurate results.

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

Indications for Use:

Deltec Cozmo® Insulin Pump with CoZmonitor™ Glucose Monitor

The Deltec CoZmonitor™ Blood Glucose Monitoring System is designed to be used only with the Deltec Cozmo® Insulin Pump to help you and your healthcare provider monitor your diabetes management program. When used properly, the monitor provides a quantitative measurement of glucose (or sugar) in whole blood. Because the monitor is powered by FreeStyle™, blood sampling can be performed using the finger, forearm, upper arm, thigh, calf or hand. All testing is performed outside of the body (in other words, *in-vitro* diagnostic use only). Use only with FreeStyle™ Test Strip and FreeStyle™ Control Solution, as other products can give inaccurate results.

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

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) Number: K031738