K101806

SUMMARY AND CERTIFICATION

510(k) SUMMARY

DEC - 7 2010

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Aidera summary for the ***Diasend System.***

SUBMITTER'S NAME:	Aidera
ADDRESS:	Aidera AB Sahlgrenska Science Park Medicinaregatan 8A SE 413 46 Goteborg Sweden
CONTACT PERSON:	Anders Sonesson
TELEPHONE NUMBER:	+46 31 741 17 85
FAX NUMBER:	+46 31 741 17 01
DATE OF SUBMISSION:	June 18, 2010

1. **Identification of device**

Proprietary Name:	Diasend
Common Name:	Accessories, Pump, Infusion System, Test, Blood Glucose, Over The Counter
Classification Status:	Class II according to Sec. 880.2910 and 862.1345
Product Codes:	MRZ, NBW

2. **Equivalent devices**
   K083221, Aidera AB, Aidera Diasend
   K072698, Confidant Inc, Confidant 2.5
   K032164, Medtronic Inc, Medtronic Minimed DDMS

3. **Description of the Device**
   Diasend is a system for transmitting data from patients' home monitoring devices and consists of a transmitter, a server database and a website available for the care provider and the patient.

   The software transmitter is a Diasend software concept developed by Aidera that may run on a computer device, e.g. desktop computer, laptop or mobile phone, designed to transmit data to the Diasend server database. Current implementation is on Windows XP.

4. **Intended use**
   Aidera Diasend is indicated for use by individuals or healthcare professionals in the home or health care facilities for transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server database to support diabetes management. The device is indicated for professional use and over-the-counter sales.

5. **Technological characteristics, comparison to predicate device.**
The Diasend system is intact except for the addition of the software transmitter compared to previously cleared device. See section 5 for a more elaborate comparison.

6. **Discussion of performance testing.**
The Diasend transmitter is tested and found to comply with applicable EMC and FCC requirements and standards.

7. **Conclusion**
Based on comparison with the predicate devices, the Aidera Diasend System is substantially equivalent to the previously cleared devices and presents no new concerns about safety and effectiveness.

8. **Indications for Use Statement**
Aidera Diasend is indicated for use by individuals or healthcare professionals in the home or health care facilities for transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server database to support diabetes management. The device is indicated for professional use and over-the-counter sales.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Anders Sonesson
CEO
AIDERA AB
Medicinaregatan 8A
SE 413 46 Goteborg
Sweden

DEC - 7 2010

Re: K101806
Trade/Device Name: Aidera Diasend System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ, NBW
Dated: November 17, 2010
Received: November 22, 2010

Dear Mr. Sonesson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

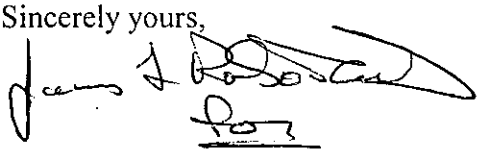
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

INDICATIONS FOR USE

510(k) Number K101806

DEC - 7 2010

Device Name:

Aidera Diasend System

Indications for Use:

Aidera Diasend is indicated for use by individuals or healthcare professionals in the home or health care facilities for transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server database to support diabetes management. The device is indicated for professional use and over-the-counter sales.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use X
(Per 21 CFR 801.109)

12/6/10

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

510(k) Number: K101806