K083225

Section 5: 510(k) Summary
(as required by 21 CFR 807.92)

Submitted by: Abbott Diabetes Care
1360 South Loop Road
Alameda, CA 94502

FEB 20 2009

Company Contact: Sarah Harrington
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Date Prepared: October 31, 2008

Trade Name: FreeStyle Aviator Insulin Delivery and Blood Glucose Monitoring System

Common/Usual Name: External insulin infusion pump and blood glucose meter

Classification Name: Insulin infusion pump and blood glucose meter
Class II: LZG, 21 CFR 880.5725
Class II: LFR, 21 CFR 862.1345

Substantially Equivalent Devices: Symphony Glucose Management System, K080639
iXL-II Diabetes Management System with Blood Glucose Meter, K042792
Aviator Insulin Pump, K071788
FreeStyle Lite Blood, K070850

Device Description

The FreeStyle Aviator Insulin Delivery and Blood Glucose Monitoring System consists of an insulin infusion pump (Aviator Pump) and a wireless remote controller (Aviator Companion). The Aviator Pump was previously cleared by the FDA on January 11, 2008 (K071788).

The Aviator Companion is a handheld, microprocessor controlled, battery powered, remote control device for the FreeStyle Aviator Insulin Delivery and Blood Glucose Monitoring System. The Aviator Companion provides an alternate user interface to the Aviator Pump which is useful when the pump is hidden under clothing.

The Aviator Companion user interface can control specific pump functions and receive pump status information. The Companion contains a large graphical LCD, jogwheel and

tactile push buttons. Both the Aviator Companion UI and the Aviator Pump UI consistently utilize text, icon and graphical presentations to prompt the user through the menus and to present data.

The Aviator Companion incorporates the FreeStyle Lite Blood Glucose Monitoring System (BGMS). The Aviator Companion has a built-in test strip port that utilizes the FreeStyle Lite Test strip. The FreeStyle Lite BGMS received FDA clearance on April 10, 2007 (K070850).

Intended Use

The FreeStyle Aviator Insulin Delivery and Blood Glucose Monitoring System is intended for continuous delivery of insulin at set and variable rates and as an aid in the management of diabetes mellitus in persons requiring insulin. The FreeStyle Aviator System is also intended for the quantitative measurement of glucose in fresh whole capillary blood (in vitro). The system is available by prescription only.

Technological Characteristics

The Aviator Companion and Aviator Pump's electronic hardware includes a radio frequency (RF) transceiver that facilitates bi-directional communication between the devices. The communication allows the user to operate the pump via the Aviator Companion. The Aviator Companion hardware architecture includes two CPUs, one primarily for user interface interactions and the other for blood glucose measurements and RF link communications.

Performance Data

Design verification testing, a blood glucose clinical study and software validation have verified the requirements stated in the specification documents. A Human Factors Study was conducted to validate the overall design of the FreeStyle Aviator Insulin Delivery and Blood Glucose Monitoring System in the hands of the user. Environmental testing includes testing for electromagnetic compatibility.

Conclusion

The performance data demonstrates substantial equivalence between the FreeStyle Aviator Insulin Delivery and Blood Glucose Monitoring System and the Symphony Glucose Management System and the iXL-II Diabetes Management System with Blood Glucose Meter. When compared to the legally marketed predicate devices, the FreeStyle Aviator Insulin Delivery and Blood Glucose Monitoring System is safe and effective for its intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sarah Harrington
Senior Regulatory Specialist
Abbott Diabetes Care Incorporated
1360 South Loop Road
Alameda, California 94502

FEB 20 2009

Re: K083225
Trade/Device Name: FreeStyle Aviator Insulin Delivery and Blood Glucose Monitoring System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG, LFR
Dated: February 5, 2009
Received: February 6, 2009

Dear Ms. Harrington:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Ginette Y. Michaud, M.D.
Acting 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):

Device Name: Freestyle Aviator Insulin Delivery and Blood Glucose Monitoring System

Indications For Use:

The FreeStyle Aviator Insulin Delivery and Blood Glucose Monitoring System is intended for continuous delivery of insulin at set and variable rates and as an aid in the management of diabetes mellitus in persons requiring insulin. The FreeStyle Aviator System is also intended for the quantitative measurement of glucose in fresh whole capillary blood (in vitro). The system is available by prescription only.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

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