Section 5: 510(k) Summary

JAN 11 2008

(as required by 21 CFR 807.92)

Submitted by:	Abbott Diabetes Care 1360 South Loop Road Alameda, CA 94502
Company Contact:	Sarah Harrington Senior Regulatory Specialist (510) 239-2732 sarah.harrington@abbott.com
Date Prepared:	June 29, 2007
Trade Name:	Aviator insulin pump
Common/Usual Name:	External Insulin Infusion Pump
Classification Name:	Class II: Insulin Infusion Pump (LZG) 21 CFR 880.5725
Substantially Equivalent Device:	Abbott Diabetes Care Insulin Pump, K051041

Device Description

The Aviator insulin pump is a microprocessor controlled, battery powered, insulin pump system. The pump continuously delivers insulin according to an individualized software plan. A proprietary, disposable syringe is used as the insulin reservoir.

The other component of the system is a disposable infusion set. There are two modes of delivery: basal and bolus. Basal delivery is a continuous infusion providing insulin the body needs to maintain target blood glucose levels under fasting conditions. To conserve power, basal delivery occurs in discrete pulses that are spaced nominally three minutes apart.

Intended Use

The Aviator insulin pump is indicated for continuous delivery of insulin, at set and variable rates and as an aid in the management of diabetes mellitus in persons requiring insulin.

Technological Characteristics

The Aviator insulin pump shares the same intended use and indications for use as the predicate device, the Abbott Diabetes Care infusion pump. Both the Aviator infusion pump and the predicate pump have two microprocessors to control and monitor drug delivery. The user interface on the Aviator was enhanced as a result of user needs.

Performance Data

Bench testing and software validation verified the requirements stated in the specification documents. A Human Factors Study was conducted to validate the overall design of the Aviator insulin pump in the hands of the user. Environmental testing includes testing for electromagnetic compatibility.

The syringe and infusion set materials will undergo biocompatibility testing, if required, in accordance to ISO 10993-1. The syringe will be sterilized to the requirements stated in ISO 11135-1994.

Conclusion

The performance data demonstrates substantial equivalence between the Aviator infusion pump and the Abbott Diabetes Care infusion pump. When compared to the legally marketed Abbott Diabetes Care infusion pump, the Aviator insulin pump 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

JAN 11 2008

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

Re: K071788
Trade/Device Name: Aviator Insulin Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: December 19, 2007
Received: December 20, 2007

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 Office of Compliance at (240) 276-0115. 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/industry/support/index.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): K071788

Device Name: Aviator Insulin Pump

Indications For Use:

The Aviator Insulin Pump is indicated for continuous delivery of insulin, at set and variable rates and as an aid in the management of diabetes mellitus in persons requiring insulin.

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

510(k) Number: K071788