Abbott Diabetes Care

Abbott Diabetes Care Inc
1360 South Loop Road
Alameda, CA 94502

t (510) 749-5400
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K070850

APR 10 2007

510(k) Summary

Per 21 CFR §807.92

Date Prepared:	March 27, 2007
Company	Abbott Laboratories
Division	Abbott Diabetes Care Inc.
Street Address	1360 South Loop Road
City, State Zip	Alameda, CA 94502
Telephone No.	510-749-5400
Fax No.	510-864-4791
Contact Person:	Dhruma Shah Tel No. 510-749-6475 Fax No. 510-864-4791 dhruma.shah@abbott.com
Proprietary Name:	FreeStyle™ Lite Blood Glucose Monitoring System
Common Name:	Blood Glucose Testing System, Glucose Dehydrogenase
Classification Name:	Glucose Test System (21 CFR §862.1345, Product code NBW, LFR)
Predicate Device:	FreeStyle Freedom™ Blood Glucose Monitoring System (K051839)

Description of the Device:

The FreeStyle™ Lite Blood Glucose Monitoring System (BGMS) utilizes coulometric biosensor technology found in the FreeStyle Lite test strip to quantitatively measure glucose concentration in whole blood samples or in FreeStyle Control Solutions. The FreeStyle Lite BGMS measures glucose electrochemically. The glucose biosensor is capable of recognizing the glucose present in whole blood by virtue of the glucose specificity of the enzyme glucose dehydrogenase (GDH) present on the glucose test strip.

Intended Use of the Device:

The FreeStyle Lite Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf and hand.

The FreeStyle Lite Blood Glucose Monitoring System is intended for use in the

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quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates or arterial blood.

Comparison to Predicate Device:

	Predicate Device (K051839)	**Subject (modified) Device**
Enzyme	PQQ dependent glucose dehydrogenase	Same
Reagent Form	Test Strip	Same
Analyte	D-Glucose	Same
Detection Method	Electrochemical-(Coulometric)	Same
Recommended Sample	Venous or capillary whole blood	Same
Calibration	Manual calibration code entry	No manual calibration code entry required
Minimum Sample Size	0.3 microliter (300 nanoliter)	Same
Measurement Range	20-500 mg/dL	Same
Measurement Time	5 seconds (average)	Same
Hematocrit Range	15% to 65%	Same
Humidity Range	5% to 90%	Same
Operating Temperature Range	40°-104° F	Same
Monitor Memory	250 test results	400 test results
Day averages	14-day average	7-, 14- & 30-day averages
Date/Time	Yes	Same
Communication	Serial Port	Same
Power Source	3V Coin Cell Battery	Same

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Assessment of Non-Clinical Performance Data:

The performance of the FreeStyle Lite Blood Glucose Monitoring System was studied in the laboratory. The results obtained during these studies demonstrated that the FreeStyle Lite Blood Glucose Monitoring System is substantially equivalent to the predicate device.

Conclusion:

Results of laboratory testing demonstrated that the performance of the FreeStyle™ Lite Blood Glucose Monitoring System is acceptable and comparable in terms of safety and effectiveness to the performance of the predicate device for blood glucose testing when used according to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 10 2007

Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502-7000
ATTN: Dhruma Shah

Re: k070850
Trade/Device Name: FreeStyle™ Lite Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: March 28, 2007
Received: March 29, 2007

Dear Ms. Shah:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number :
(if known) K070850

Device Name: FreeStyle™ Lite Blood Glucose Monitoring System

Indications for Use:

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Prescription Use _____ AND/OR Over-The-Counter Use __X__
(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

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K070850