K051802

AUG 9 - 2005

ABBOTT

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

Telephone 510-749-5400
Facsimile 510-239-2799
www.abbott.com

510(k) Summary

Per 21 CFR §807.92

Company	Abbott Laboratories / TheraSense Inc.
Division	Abbott Diabetes Care
Street Address	1360 South Loop Road
City, State Zip	Alameda, CA 94502
Phone	510-749-5400
Contact Person:	Kimberley Kline 510-749-5478 kimberley.kline@abbott.com
Proprietary Name:	FreeStyle Connect™ Blood Glucose Monitoring System
Common Name:	Blood Glucose Meter and Reagent Test Strips
Classification Number:	21 CFR §862.1345
Predicate Device:	Precision PCx Blood Glucose Monitor and FreeStyle 600 Blood Glucose Test Strips
Date Prepared:	June 30, 2005

Description of the Device:

The FreeStyle Connect monitor utilizes coulometric biosensor technology found in the FreeStyle Connect test strip to quantitatively measure glucose concentration in whole blood samples or in FreeStyle Control Solutions. The FreeStyle Connect 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 Connect Blood Glucose Monitoring System is intended for invitro diagnostic use for the quantitative measurement of glucose in fresh capillary, venous, arterial and neonatal whole blood samples. The FreeStyle Connect Blood Glucose Monitoring System is for testing outside the body (*in vitro* diagnostic use). The FreeStyle Connect Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor blood glucose levels.

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Comparison to Predicate Device:

	Predicate Devices	Subject (modified) Device
Company	Abbott Laboratories	Same
Division	Abbott Diabetes Care	Same
510(k) Reference	K022941 and K050500	Current Submission
Proprietary Name:	Precision PCx Point of Care Monitor and FreeStyle 600 Blood Glucose Test Strips	Same
Common Name:	Blood Glucose Monitor and Reagent Test Strips	Same
Classification Number:	21 CFR §862.1345	Same
Intended Use	Quantitative measurement of blood glucose concentrations	Same
Single Use?	Yes, test strips are single use	Same
Sterilized?	No	Same

Performance Studies:

The performance of the FreeStyle Connect BGMS was studied in the laboratory. The results obtained during these studies demonstrated that the FreeStyle Connect BGMS is substantially equivalent to the predicate devices.

Conclusion:

Results of laboratory testing demonstrated that the performance of the FreeStyle Connect BGMS is acceptable and comparable to the performance of the predicate devices for blood glucose testing when used according to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kimberly Kline
Senior Regulatory Associate
Abbott Laboratories
Abbott Diabetes Care
1360 South Loop Road
Alameda, CA 94502

AUG 9 - 2005

Re: k051802
Trade/Device Name: FreeStyle Connect Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: July 29, 2005
Received: August 1, 2005

Dear Ms. Kline:

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 (301) 594-3084. 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,

for: Carol C. Benson, M.A.
Acting 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

510(k) Number (if known):

Device Name: FreeStyle Connect™ Blood Glucose Monitoring System

Indications for Use:

The FreeStyle Connect Blood Glucose Monitoring System is intended for in vitro diagnostic use for the quantitative measurement of glucose in fresh capillary, venous, arterial and neonatal whole blood samples. The FreeStyle Connect Blood Glucose Monitoring System is for testing outside the body (*in vitro* diagnostic use). The FreeStyle Connect Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor blood glucose levels.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 807 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) K051802