K051213

Attachment 4

510(k) Summary

Per 21 CFR §807.92

Company	Abbott Laboratories
Division	Abbott Diabetes Care
Street Address	1360 South Loop Road
City, State Zip	Alameda, CA 94502
Phone	510-749-6360
Contact Person:	Andrea L. Ruth 510-749-6360 andrea.ruth@abbott.com
Proprietary Name:	MediSense Optium Plus and Precision Xtra Plus Blood Glucose Test Strips
Common Name:	Blood Glucose Test Strips
Classification Number:	21 CFR §862.1345
Predicate Device:	MediSense Optium Plus and Precision Xtra Plus Blood Glucose Test Strips
Date Prepared:	May 11, 2005

Description of the Device:

The Precision Xtra™ Advanced Diabetes Management System utilizes amperometric biosensor technology to generate a current. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measure of glucose in whole blood and control solutions.

Intended Use of the Device:

Blood Glucose Test Strips are intended for in-vitro diagnostic use in the quantitative measurement of glucose in fresh whole blood for self-testing by lay users (e.g., from the finger, forearm, upper arm or base of thumb), or by health care professionals. The test strip is to be used for monitoring blood glucose concentrations in persons with diabetes and other conditions.

Comparison to Predicate Device:

	Predicate Device	Subject (modified) Device
Company	Abbott Laboratories	Same
Division	Abbott Diabetes Care	Same
510(k) Reference	K023256	Current Submission
Proprietary Name:	MediSense Optium Plus and Precision Xtra Plus Blood Glucose Test Strips	Same
Common Name:	Blood Glucose 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 strips using various diabetes monitoring systems was studied in the laboratory. The studies demonstrated that lay users can obtain blood glucose results that are substantially equivalent to the current methods for blood glucose measurements.

Conclusion:

Results of laboratory testing demonstrate that the performance of the Precision Xtra Diabetes Test Strip is acceptable and comparable 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

Ms. Andrea L. Ruth, RAC
Senior Associate, Regulatory Affairs
Abbott Laboratories
TheraSense, Inc.
1360 South Loop Road
Alameda, CA 94502

MAY 2 7 2005

Re: k051213
Trade/Device Name: Optium Plus Blood Glucose Test Strips and
Precision Xtra Plus Blood Glucose Test Strips
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: LFR, NBW
Dated: May 11, 2005
Received: May 17, 2005

Dear Ms. Ruth:

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) 276-0484. 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,

Carol C. Benson

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): K051213

Device Name: Optium Plus Blood Glucose Test Strips and
Precision Xtra Plus Blood Glucose Test Strips

Indications For Use: The Precision Xtra / MediSense Optium / Precision Easy / MediSense Optium Easy Blood Glucose Test Strip is intended for outside-the-body (in-vitro diagnostic) use. The strip is indicated for the quantitative measurement of glucose in fresh capillary blood for self-testing by lay users (e.g., from the finger, forearm, upper arm or base of thumb), or by health care professionals. The test strip is to be used for monitoring blood glucose concentrations in persons with diabetes and other conditions.

Prescription Use _____ 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

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K051213