APR 1 5 2004

K040314

MediSense®

510(k) Summary

(as required by 21 CFR 807.92)

Submitted by: Tracey H. Wielinski RAC
Strategic Quality Assurance and Regulatory Affairs Manager
Abbott Laboratories, MediSense Products
4A Crosby Drive
Bedford, MA 01730

Device Name: Precision Xtra™ Advanced Diabetes Management System

Common Name: Whole Blood Glucose and Ketone Test System

Classification: Glucose Test System
Class II per 21 CFR 862.1345

Ketone Test System
Class I per 21 CFR 862.1435

Product Code: NBW, LFR, JIN

Predicate Device: Precision Xtra™ Advanced Diabetes Management System, K983504

Description: 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 or β-hydroxybutytate (β-ketone) present in the sample, providing a quantitative measure of glucose or β-ketone in whole blood and control solutions.

Indications for Use: The Precision Xtra Advanced Diabetes Management System is intended for in vitro diagnostic use (i.e., external use only) for the quantitative measurement of glucose in fresh capillary whole blood. The Precision Xtra is also intended for the quantitative measurement of β-hydroxybutyrate (β-ketone) in fresh capillary whole blood. The Precision Xtra system is indicated for home (lay user) or professional use in the management of Patients with diabetes.

The Precision Xtra System may also be used for the quantitative measurement of glucose in venous, arterial, or neonatal whole blood and ketone in venous blood, provided the sample is used within 30 minutes after collection.

Comparison to Predicate Device: The modified Precision Xtra™ Advanced Diabetes Monitoring System uses the same fundamental scientific technology and has the same intended use as the predicate Precision Xtra Advanced Diabetes Management System (K983504).

Performance Studies: The performance of the Precision Xtra Diabetes Monitoring System was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that lay users can obtain blood glucose and blood β-Ketone results that are substantially equivalent to the current methods for blood glucose and blood β-ketone measurements.

Conclusion: Results of laboratory and clinical testing demonstrate that the performance of the Precision Xtra Diabetes Monitoring System, when used according to the intended use stated above, is acceptable and comparable to the performance of the previously mentioned predicate device for blood glucose and blood β-ketone testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 1 5 2004

Ms. Tracey H. Wielinski, RAC
Strategic Quality Assurance and Regulatory Affairs Manager
Abbott Laboratories
MediSense Products
4-A Crosby Drive
Bedford, MA 01730

Re: k040814
Trade/Device Name: Precision Xtra™ Advanced Diabetes Management System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LFR, JIN
Dated: March 29, 2004
Received: March 30, 2004

Dear Ms. Wielinski:

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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, 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

510(k) Number (if known):

Device Name: Precision Xtra™ Advanced Diabetes Management System

Indications For Use:

The Precision Xtra Advanced Diabetes Management System is intended for in vitro diagnostic use (i.e., external use only) for the quantitative measurement of glucose in fresh capillary whole blood. The Precision Xtra is also intended for the quantitative measurement of β-hydroxybutyrate (β-ketone) in fresh capillary whole blood. The Precision Xtra system is indicated for home (lay user) or professional use in the management of Patients with diabetes.

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

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040814