K983504

JUL -9 1999

Summary of Safety and Effectiveness

Submitted by: Denise Haley
Regulatory Affairs Specialist
MediSense, Inc.
4A Crosby Drive
Bedford, MA 01730

Device Name: Precision™ Xtra™ Advanced Diabetes Management System

Common Name: Self-Monitoring Blood Glucose and Ketone System

Classification: Glucose Test System
Class II per 21 CFR 862.1345

Ketones Test System
Class I per 21 CFR 862.1435

Predicate Devices:
Precision QID® Blood Glucose Testing System--K963676
Precision QID® and Precision G® Blood Glucose Test Strip--K945887, K962295, K971812
GDS Stat-Site Meter/GDS KETOSITE® Blood Ketone Test--K911801
Sigma Diagnostics β-Hydroxybutyrate Procedure No. 310-UV--K850368

Description: The Precision™ Xtra™ Advanced Diabetes Management System for Blood Glucose and Ketone Testing utilizes amperometric biosensor technology to generate a current. The size of the current is proportional to the amount of glucose (or Beta-Hydroxybutyrate ketone) present in the sample, providing a quantitative measure of glucose (or ketone) in whole blood and control solutions.

Intended Use: The Precision Xtra Advanced Diabetes Management System is intended for in vitro diagnostic use (i.e. for external use only) for the quantitative measurement of glucose and/or ketone in fresh capillary whole blood. The Precision Xtra is for home (lay user) or professional use.

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.

Comparison to Predicate Device:

The Precision Xtra Advanced Diabetes Management System has equivalent technological characteristics as the Precision QID Blood Glucose Testing System (K963676, K971812) and the Precision G Blood Glucose Testing System (K963676). The Precision Xtra also has the same intended use as the Precision QID and Precision G Systems for glucose testing and the GDS Ketosite Test Card on the GDS Stat-Site Meter(K911801) and Sigma β-Hydroxybutyrate Procedure 310-UV (K850368) for ketone testing.

Performance Studies:

The performance of the Precision Xtra Diabetes Management 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 ketone results that are substantially equivalent to the current methods for blood glucose and ketone measurements, which include the predicate devices listed above.

Conclusion:

Results of laboratory and clinical testing demonstrate that the performance of the Precision Xtra Advanced Diabetes Management System, when used according to the intended use stated above, is acceptable and comparable to the performance of the previously mentioned predicate devices for blood glucose and ketone testing. In addition, results of clinical performance testing demonstrate that trained operators and lay users obtain equivalent whole blood glucose and ketone results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL -9 1999

Ms. Denise Haley
Regulatory Affairs Specialist
Abbott Laboratories
MediSense Products
4A Crosby Drive
Bedford, Massachusetts 01730-1402

Re: K983504
Trade Name: Precision™ Xtra™ Advanced Diabetes Management System
Regulatory Class: II
Product Code: CGA
Dated: April 29, 1999
Received: May 3, 1999

Dear Ms. Haley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K983504

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. for external use only) for the quantitative measurement of glucose and/or ketone in fresh capillary whole blood. The Precision Xtra System is for home (lay user) or professional use.

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.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K983504

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The-Counter Use ✓
(Per 21 CFR 801.108)