SEP 9 2002

K020182

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by: Janet Connolly, RAC
Sr. Regulatory Affairs Specialist
Abbott Laboratories, MediSense Products
4A Crosby Drive
Bedford, MA 01730-6230

Device Name: MediSense® Precision® Easy / MediSense® Optium™ Easy Blood Glucose Monitoring System

Common Name: Self-Monitoring Blood Glucose System

Classification: Glucose Test System
Class II per 21 CFR 862.1345

Predicate Device: Precision QID® Blood Glucose Testing System, K944195, K971812,

Description: The MediSense Precision Easy / MediSense Optium Easy Blood Glucose Monitoring System for blood glucose testing 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: The MediSense Precision Easy / MediSense Optium Easy Blood Glucose Monitoring System is intended for outside-the-body (*in-vitro* diagnostic) use. The system is indicated for the quantitative measurement of glucose in fresh whole blood for self-testing by lay users (e.g., from the finger), or by health care professionals.

Comparison to Predicate Device: The MediSense Precision Easy / MediSense Optium Easy Blood Glucose Monitoring System has equivalent technological characteristics as the Precision QID Blood Glucose Testing System (K944195, K971812). The Precision Easy also has the same intended use as the Precision QID.

Performance Studies: The performance of the MediSense Precision Easy / MediSense Optium Easy Blood Glucose 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 results that are substantially equivalent to the current methods

for blood glucose measurements, which include the predicate devices listed above.

Conclusion: Results of laboratory and clinical testing demonstrate that the performance of the MediSense Precision Easy / MediSense Optium Easy Blood Glucose Monitoring 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 testing. In addition, results of clinical performance testing demonstrate that trained operators and lay users obtain equivalent whole blood glucose results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Janet Connolly, RAC
Sr. Regulatory Affairs Specialist
Abbott Laboratories, MediSense Products
4A Crosby Drive
Bedford, MA 01730-1402

Re: k022182
Trade/Device Name: MediSense® Precision® Easy/MediSense® Optium™ Easy Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: July 2, 2002
Received: July 3, 2002

Dear Ms. Connolly:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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): K022182

Device Name: MediSense® Precision® Easy / MediSense® Optium™ Easy Blood Glucose Monitoring System

Indications For Use:

The MediSense Precision Easy / MediSense Optium Easy Blood Glucose Monitoring System is intended for outside-the-body (*in-vitro diagnostic*) use. The system is indicated for the quantitative measurement of glucose in fresh whole blood for self-testing by lay users (e.g., from the finger), or by health care professionals. The MediSense Precision Easy / MediSense Optium Easy Blood Glucose Monitoring System is to be used for the monitoring of blood glucose concentrations in persons with diabetes and other conditions.

Liam Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022182

(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)

Liam Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022182