MAR 2 5 2004

K040628

MediSense®

510(k) Summary
(as required by 21 CFR 807.92)

Submitted by: **Graham A. L. Baillie**
Senior Regulatory Specialist
Abbott Laboratories, MediSense Products
4A Crosby Drive
Bedford, MA 01730

Device Name: **Precision Link® Diabetes Data Management System**

Common Name: **Data Management System**
(Accessory to Blood Glucose Testing System)

Classification: **Glucose Test System**
Class II per 21 CFR 862.1345

Product Code: **NBW**

Predicate Device: **Precision Link® Blood Glucose Data Management System, K952279**

Description: The Precision Link Diabetes Data Management System is a blood glucose data management software system designed to operate on a Windows/Intel/IBM compatible platform.

Data is transferred from the glucose meter via a serial cable to a PC, then processed and presented in various user selected graphical formats. Precision Link is available for home and professional use.

Intended Use: The Precision Link systems are intended to collect and report information to assist with diabetes management.

Comparison to Predicate Device: The Precision Link Diabetes Data Management System uses the same fundamental scientific technology and has the same intended use as the predicate Precision Link Blood Glucose Data Management System, K952279.

Performance Studies:

System hardware and software verification testing confirms that the modified Precision Link Diabetes Data Management System is equivalent to the currently marketed Precision Link Blood Glucose Data Management System. The changes have been verified and do not adversely affect safety or effectiveness.

System verification testing confirms that Precision Link will perform as intended when used in accordance with device labeling.

Conclusion:

Test results demonstrate that the performance of the Precision Link Diabetes Data Management System, when used according to the intended use stated above, is acceptable and substantially equivalent to the performance and safety characteristics of the previously mentioned predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 25 2004

Mr. Graham A. L. Baillie
Senior Regulatory Affairs Specialist
Abbott Laboratories
MediSense Products
4-A Crosby Drive
Bedford, MA 01730

Re: k040628
Trade/Device Name: Precision Link® Diabetes Data Management System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: March 9, 2004
Received: March 10, 2004

Dear Mr. Baillie:

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: K040628

Device Name: **Precision Link® Diabetes Data Management System**

Indications For Use: The MediSense Precision Link® Diabetes Data Management System lets you view and analyze results of a MediSense Products meter. It enables the users to upload blood glucose and blood ketone results from a MediSense Products meter, view the information, and print the information using various report formats. Precision Link is designed for use by people with diabetes and/or healthcare professionals that have a basic understanding of personal computers

Prescription Use _____	AND/OR	Over-the-Counter-Use ___X___
(per 21 CFR 801 Subpart D)		(21CFR 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)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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