DEC 8 1998

K982303

Summary of Safety and Effectiveness

Submitted by:

Michael Halpin
Manager, Regulatory Affairs and Quality Systems
MediSense, Incorporated
4A Crosby Drive
Bedford, Massachusetts 01730

Device Name: Precision·G Plus Point of Care Management System for Blood Glucose Testing

Common Name: Blood Glucose Testing System

Classification: Glucose Test System
Class II per 21 CFR 862.1345

Predicate Devices: Precision·G® Blood Glucose Testing System--K963676
Precision QID® Blood Glucose Testing System--K944195
Precision QID® and Precision·G® Blood Glucose Test Strip--K945887, K962295, K971812
Johnson and Johnson Surestep Pro System -- K970556

Description: The Precision·G Plus Point of Care Management 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 Precision·G Plus Point of Care Management System is intended for the in vitro diagnostic use (i.e. for external use only) for the quantitative measurement of glucose in fresh capillary whole blood. The Precision·G Plus Point of Care Management System is for home (lay user) or professional use.

The product may also be used by healthcare professionals for the quantitative measurement of glucose in venous, arterial or neonatal whole blood, provided the sample is used within 30 minutes.

Comparison to Predicate Device: The proposed Precision·G Plus Point of Care Management System has equivalent technological characteristics and the same intended use as both the Precision·G® Blood Glucose Testing System (K963676, K971812) and the Precision QID® Blood Glucose Testing System (K944195, K971812). In addition, the Precision G Plus Point of Care Management system is substantially equivalent

to an additional competitive predicate device, the Johnson and Johnson Surestep Pro Blood Glucose Monitoring System (K970556).

Performance Studies:

The performance of the Precision G Point of Care Management System was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that user can obtain blood glucose results that are substantially equivalent to the current methods for blood glucose measurement including the predicate devices named above.

Conclusion:

Results of laboratory and clinical testing demonstrate that the performance of the Precision G Point of Care Management system when used according to the intended use stated above is acceptable and comparable to the performance of the predicate devices mentioned above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Michael Halpin
Manager, Regulatory Affairs
and Quality Systems
MediSense, Incorporated
4A Crosby Drive
Bedford, Massachusetts 01730

DEC 8 1998

Re: K982303
Trade Name: Precision-G Plus Point of Care Management System for Blood Glucose Testing
Regulatory Class: II
Product Code: CGA
Dated: June 30, 1998
Received: July 1, 1998

Dear Mr. Halpin:

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 have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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):

Device Name: Precision·G Plus Point of Care Management System for Blood Glucose

Indications For Use:

The Precision·G Plus Point of Care Management System for Blood Glucose is intended for the in vitro diagnostic use (i.e. for external use only) for the quantitative measurement of glucose in fresh capillary whole blood. The Precision·G Plus Point of Care Management System is for home (lay user) or professional use.

The product may also be used by healthcare professionals for the quantitative measurement of glucose in venous, arterial or neonatal whole blood, provided the sample is used within 30 minutes.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983703