

AUG - 8 1997

Summary of Safety and Effectiveness

K971812

Submitted by: Michael Halpin
Manager of Regulatory Affairs
MediSense, Inc.
4A Crosby Drive
Bedford MA 01730

Device Name: Precision QID® and Precision G Blood Glucose Test Strip

Common Name: Reagent test strips for Blood Glucose

Classification: "Glucose Test System" - Class II per CFR 862.1345

Predicate Devices: Precision QID® Blood Glucose Test Strip - K945887, K962295
Precision G Blood Glucose Testing System - K963676
Accu-Chek Advantage Test Strips - K951887, K954833

Description: The Precision QID and Precision G Blood Glucose Test Strips are identical in test strip design. Both test strips utilize amperometric biosensor technology to quantitatively measure glucose in whole blood and control solutions. The Precision QID Blood Glucose Test Strips are for use with the Precision QID Blood Glucose Testing System and are also compatible with the MediSense 2 Card and Pen Blood Glucose Testing Systems. The Precision G Blood Glucose Test Strip is only for use with the Precision G Blood Glucose Testing System.

Intended Use: The Precision QID Blood Glucose Testing System is intended for in vitro diagnostic use (i.e., for external use only) for the quantitative measurement of glucose in fresh capillary whole blood. For home or professional use with the Precision QID Blood Glucose Sensor. Compatible with the MediSense 2 Card and Pen Blood Glucose Sensors, and the Companion 2 Card and Pen Blood Glucose Sensors.

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

The Precision G Blood Glucose Testing System is intended for in vitro diagnostic use (i.e., for external use only) for the quantitative measurement of glucose in fresh whole capillary blood. The Precision G Blood Glucose Testing System is intended for home or professional use.

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

**Comparison to
Predicate Device:**

The proposed Precision QID and Precision G Blood Glucose Test Strip have technological characteristics equivalent to those of the predicate Precision QID Blood Glucose Test Strip (K945887, K962295) and predicate Precision G Blood Glucose Testing System (K963676). The proposed Precision QID and Precision G Test Strip is comparable in form, function, material composition, manufacturing process, and intended use to the predicate Precision QID Test Strip and Precision G Test Strip. In addition the intended use for the proposed Precision QID and Precision G Test Strip is identical to the intended use of another predicate device, the Accu-Chek Advantage Test Strip (K951887, K954833).

**Performance
Studies:**

The performance of the Precision QID and Precision G Test Strip 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 QID and Precision G Blood Glucose Test Strip when used according to the intended use stated above is acceptable and comparable to the performance of the predicate devices including the Precision QID Blood Glucose Test Strip (K945887, K962295), the Precision G Blood Glucose Testing System (K963676), and the Accu-Chek Advantage Test Strip (K951887, K954833).



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Michael G. Halpin
• Manager
Regulatory Affairs and Compliance
Medisense, Inc.
4A Crosby Drive
Bedford, MA 01730

Re: K971812/S001
Precision QID® and Precision G Blood Glucose Test Strip
Regulatory Class: II
Product Code: CGA
Dated: July 31, 1997
Received: August 4, 1997

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 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 requirement, 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.

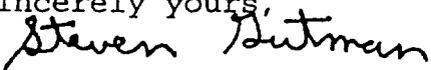
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsmamain.html>".

Sincerely yours,



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): K945887; K962295

Device Name: Precision QID Blood Glucose Testing System

Indications For Use:

The Precision QID Blood Glucose Testing System is intended for in vitro diagnostic use (i.e., for external use only) for the quantitative measurement of glucose in fresh capillary whole blood. For home or professional use with the Precision QID Blood Glucose Sensor. Compatible with the MediSense 2 Card and Pen Blood Glucose Sensors, and the Companion 2 Card and Pen Blood Glucose Sensors.

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

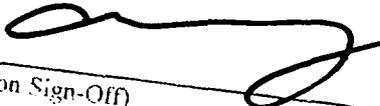
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.108)

or

Over-The-Counter Use


(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K971812