K983253

NOV 20 1998

CONFIDENTIAL

Summary of Safety and Effectiveness

Submitted by:

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MediSense, Inc.
4A Crosby Drive
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Device Name: Precision A1c™ Home HbA1c Sample Collection Kit

Common Name: Self-monitoring hemoglobin A1c (glycosylated hemoglobin) capillary blood sample collection kit; dried blood spot (DBS) card

Classification: Glycosylated Hemoglobin Assay
(Class II per 21 CFR 864.7470)

Predicate Devices:
EZCHEK™/HbA1c Sample Collection Kit--K971919
Self-Assure®/GHb--K861697/A
Accu-Chek™ A1c Hemoglobin Test--K974491
Roche Cobas® Integra HbA1c--K961824
Roche Unimate HbA1c Reagent--K952337/S1
Bio-Rad Diamat Glycosylated Hemoglobin Analyzer System--K851636

Description:

The Precision A1c Home HbA1c Sample Collection Kit contains the materials necessary to collect a capillary blood sample from a finger-stick to a piece of filter paper and mail it to a clinical laboratory for the determination of percent hemoglobin A1c (also known as glycohemoglobin or glycosylated hemoglobin).

The Precision A1c sample collection kit contains a lancet, patient information sheet, instruction sheet, alcohol pad, gauze pad, bandage, pre-paid mailing envelope, and a blood sample collection card (inside a zip-locked foil pouch containing a desiccant).

Intended Use:

The Precision A1c Home HbA1c Sample Collection Kit is intended to be a home-use or office-use device for the collection of a capillary blood sample on a blood sample collection card for in vitro diagnostic laboratory evaluation of the amount of HbA1c (glycosylated hemoglobin). This collection device will be used to monitor long-term blood glucose control in patients with diabetes mellitus.

The Precision A1c sample collection device will be marketed over-the-counter. This kit is not indicated for the diagnosis of diabetes mellitus.

Comparison to Predicate Device: The proposed Precision A1c Home HbA1c Sample Collection Kit has components, technological characteristics, and an intended use equivalent to predicate HbA1c collection devices such as the EZCHEK™/HbA1c (K971919), Accu-Chek™ A1c Hemoglobin Test and the Self-Assure®/GHb (K861697/A) Sample Collection Kits. The use of this kit affects only the sample collection stage of the testing process.

The HbA1c results obtained from blood samples collected with the Precision A1c Home HbA1c Sample Collection Kit were equivalent to results obtained from whole blood samples analyzed on the Roche Cobas Integra, HbA1c Cassette (K961824), Roche Cobas Mira, Unimate Reagent (K952337/S1) and Bio-Rad Diamat Glycosylated Hemoglobin Analyzer System (K851636).

Performance Studies:

Performance studies were conducted on blood samples collected with Precision A1c cards by both lay users and trained operators at three sites. A corresponding venous whole blood sample was also collected from each patient in the study as a control sample to compare whole blood results to those obtained from blood samples collected with the Precision A1c card. Samples from two clinical sites were then mailed to LabOne for determination of percent glycohemoglobin. Samples collected by the University of Missouri were not mailed but were tested on-site.

Performance studies included:

- -Correlation of %HbA1c values obtained with whole blood vs. samples collected on the Precision A1c card by trained operators.
- -Correlation of %HbA1c values obtained with whole blood vs. samples collected on the Precision A1c card by lay users.
- -Correlation of %HbA1c values obtained by trained operators vs. lay users on samples collected with the Precision A1c card.

The performance results from all sites combined are described below:

	Trained Operator using the Precision A1c Sample Collection Kit vs. Whole Blood	Lay User using the Precision A1c Sample Collection Kit vs. Whole Blood	Trained Operator vs. Lay User--both using the Precision A1c Sample Collection Kit
Correlation Coefficient	0.993	0.989	0.996
Slope	1.019	1.016	0.999
y-Intercept	-0.02	-0.05	-0.04
Sy.x	0.22	0.27	0.18
Bias	0.12	0.07	-0.05
Mean Absolute % Bias	2.50	2.77	1.76
N	258	259	259

Conclusion:

Both the correlation coefficients and slopes obtained in this study were close to 1.000 and the y-intercepts close to 0.0. Results indicate excellent correlation between venous whole blood samples and capillary blood samples (collected with the Precision A1c Kit) and analyzed by the Roche Cobas Systems. In addition, equivalent results were achieved by lay users and trained operators when compared against each other.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 20 1998

Ms. Denise Haley
Regualtory Affairs Specialist
MediSense, Inc.
4A Crosby Drive
Bedford, Massachusetts 01730

Re: K983253
Trade Name: Precision A1c™ Home HbA1c Sample Collection Kit
Regulatory Class: II
Product Code: LCP
Dated: September 15, 1998
Received: September 16, 1998

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 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): K983253

Device Name: Precision™ A1c Home HbA1c Sample Collection Kit

Indications For Use:

The Precision A1c Home HbA1c Sample Collection Kit is intended to be a home-use or office-use device for the collection of a capillary blood sample on a blood sample collection card for in vitro diagnostic laboratory evaluation of the amount of HbA1c (glycosylated hemoglobin). This collection device will be used to monitor long-term blood glucose control in patients with diabetes mellitus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Both

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983253