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DEC 13 2002

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K022661

807.92 (a)(1): Name: Metrika, Inc.
Address: 510 Oakmead Parkway
Sunnyvale, CA 94085
Phone: (408) 524-2255
FAX: (408) 524-2252
Contact: Joel M. Blatt, Ph.D.

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name: A1cNow™ for Home Use

Common Name: percent hemoglobin A1c (percent glycosylated hemoglobin)

Classification: assay, glycosylated hemoglobin 21 CFR 864.7470

807.92 (a)(3): Identification of the legally marketed predicate device

A1cNow™ for Home Use is substantially equivalent to A1cNow™ for Rx Home Use (K020234). The only difference between the two tests is in the intended use; A1cNow™ for Home Use will be marketed directly to the diabetic consumer, while A1cNow™ for Rx Home Use requires a prescription. The device and procedural steps are identical.

807.92 (a)(4): Device Description

A1cNow™ for Home Use is a four-channel reflectance photometer that incorporates microelectronics, optics, and dry-reagent chemistry strips within a self-contained, integrated, single-use device. An unmeasured whole blood mixture (diluted) is applied directly to the sample port, and results are displayed in numeric form on the device's liquid crystal display after eight minutes. Having no switches or buttons, the device self-activates upon addition of the sample.

807.92 (a)(4): Device Description (continued)

A1cNow™ for Home Use utilizes both immunoassay and chemistry technology to measure HbA1c and total hemoglobin, respectively. Upon the addition of a diluted blood sample, blue microparticles conjugated to anti-HbA1c antibody migrate along the reagent strips. The amount of blue microparticles captured on the strips reflects the amount of HbA1c in the sample.

For the total hemoglobin portion of the assay, the dilution of sample converts Hb to met-Hb, which is red-brown in color. The intensity of the red-brown color measured on the reagent strips is proportional to the concentration of hemoglobin in the sample.

807.92 (a)(5): Intended use

The A1cNow™ test provides quantitative measurement of the percent of glycated hemoglobin (% HbA1c) levels in fingerstick (capillary) whole blood samples. The test is for home use by people with diabetes to monitor glycemic control.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

Comparisons Between A1cNow™ for Home Use and A1cNow™ for Rx Home Use

CHARACTERISTIC	A1cNow™ for Home Use	A1cNow™ for Rx Home Use K020234, K000885
Intended Use	Quantitative measurement of the percent of glycated hemoglobin	Quantitative measurement of the percent of glycated hemoglobin
Indications for Use	Used in the management and treatment of diabetes, for monitoring long term glycemic control	Used in the management and treatment of diabetes, for monitoring long term glycemic control
Risk to Patient	Not a critical analyte - reflects glucose monitoring over time	Not a critical analyte – reflects glucose monitoring over time
Sample	Whole blood	Whole blood
Visual Display	LCD readout	LCD readout
Hemolysate Preparation	Manual (Sample Dilution Kit)	Manual (Sample Dilution Kit)
Calibration	Not required by end-user; each unit is factory calibrated	Not required by end-user; each unit is factory calibrated
Methodology	Immunoassay	Immunoassay
Detection Method	Four-channel reflectance photometer	Four-channel reflectance photometer
Testing Environment	Home Use	Rx Home Use
Throughput	8 minutes per sample	8 minutes per sample
Precision	Percent coefficient of variation: approximately 5.4 %CV	Percent coefficient of variation: approximately 6.4 %CV
Accuracy (estimated bias)	Biases of 1-2% (±0.1 %A1C) across the range of 6 %A1C to 8 %A1C	Biases of 2-3% across the range of 6% A1C to 8 %A1C
Accuracy (total error)	Bias plot reveals 95% confidence limits of –0.9 %HbA1c to +1.1 %HbA1c	Bias plot reveals 95% confidence limits of –0.8 %HbA1c to +1.2 %HbA1c
NGSP Certification Status	A1cNow™ NGSP-certified as of June 1, 2002	Previous submissions predated NGSP certification

The differences in the two testing platforms do not raise new issues of safety and effectiveness.

807.92 (b)(1): Brief Description of Nonclinical Data

Studies were performed that evaluated linearity, hematocrit tolerance, precision, and specificity. Results from these studies were presented in a previous submission, and were not repeated for this submission.

A1cNow™ is linear between 3% and 13% HbA1c. The test produces suitable results with sample hematocrits between 20% and 60% PCV (packed cell volume). The test's imprecision is approximately 5.4 %CV, and the assay is not affected by high levels of various biological compounds, various common over-the-counter therapeutics, and oral antihyperglycemic agents.

807.92 (b)(2): Brief Description of Clinical Data

In clinical studies with approximately 300 untrained subjects, A1cNow™ was 98% accurate. The average estimated bias between the consumer's results and results obtained by a standard laboratory method was less than 2%.

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

A1cNow™ was evaluated for nonclinical and clinical performance characteristics in comprehensive studies. These studies demonstrated that the test is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 13 2002

Erika Ammirati, R.A.C., MT (ASCP)
Clinical/Regulatory Consultant to Metrika
Metrika, Inc.
510 Oakmead Parkway
Sunnyvale, CA 94086

Re: k022661
Trade/Device Name: Metrika A1cNow® for Home Use
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP
Dated: October 17, 2002
Received: October 18, 2002

Dear Ms. Ammirati:

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). 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K022661

Device Name: A1cNow™

Indications for Use:
The A1cNow™ test provides quantitative measurement of the percent of glycated hemoglobin (%HbA1c) levels in capillary (fingerstick) whole blood samples. The test is for home use by people with diabetes to monitor glycemic control.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022661

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over –the-Counter Use ✓
(Per 21 CFR 801.109)