



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 9 2005

Erika Ammirati
Regulatory Consultant
Metrika, Inc
510 Oakmead Parkway
Sunnyvale, CA 94086

Re: k033847

Trade/Device Name: A1cNow®
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP
Dated: December 10 2003
Received: December 11 2003

Dear Ms. Ammirati:

This letter corrects our substantially equivalent letter of December 23, 2003 regarding the Metrika, Inc A1cNow® for prescription and home use. The Indications for Use that accompanies the clearance letter was marked erroneously as "Prescription Use" only. A corrected Indication for Use form with both Prescription Use and Over the Counter use is included.

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 (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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. 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/industry/support/index.html>

Sincerely yours,



Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Indications for Use

510(K) Number (if known): K033847

Device Name: A1cNow®

Indications for Use:

The A1cNow® test provides quantitative measurement of the percent of glycated hemoglobin (%HbA1c, %A1C) levels in whole blood samples. The test is for home use and professional use for monitoring glycemic control in people with diabetes.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 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 (OVD)

Carol C. Benham
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K033847

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