



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Medica Corporation
c/o Dr. Photios Makris
5 Oak Park Drive
Bedford, MA 01730

NOV 15 2011

Re: k111005
Trade Name: Easy RA Ethyl Alcohol Reagent, Calibrator, and QC Material
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol Test System
Regulatory Class: Class II
Product Codes: DIC, DLJ, LAS
Dated: August 1, 2011
Received: November 7, 2011

Dear Dr. Makris:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment 1

Indications for Use

510(k) Number (if known): K111005

Device Name: EasyRA Ethyl Alcohol (EtOH) Reagent

Indications For Use: The EasyRA EtOH reagent is intended for the quantitative measurement of Alcohol (EtOH) in human urine, using MEDICA's EasyRA Chemistry Analyzer in clinical laboratories. Alcohol measurements are used for the diagnosis and treatment of alcohol intoxication and poisoning.

Device Name: EasyRA Ethyl Alcohol (EtOH) Calibrator

Indications For Use: The EasyCal Ethanol Calibrator is intended for in-vitro diagnostic use for the calibration of the ethyl alcohol assay on the EasyRA Chemistry Analyzer for the quantitative determination of ethyl alcohol in urine.

Device Name: EasyRA Ethyl Alcohol (EtOH) QC Material

Indications For Use: The EasyQC Ethanol quality control material is intended for in-vitro diagnostic use for the validation of the ethyl alcohol assay, which is used on the EasyRA Chemistry Analyzer for the quantitative determination of ethyl alcohol in urine.

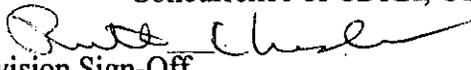
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 111005
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