



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

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

JUL 12 2011

Re: k111036

Trade/Device Name: EasyRA High Density Lipoproteins (HDL) Cholesterol Reagent, EasyRA Low Density Lipoproteins (LDL) Cholesterol Reagent, EasyRA Cholesterol (CHOL) Reagent, EasyRA Triglycerides (TRIG) Reagent

Regulation Number: 21 CFR 862.1475

Regulation Name: Lipoprotein Test System

Regulatory Class: Class I, meets limitations per 21 CFR 862.9(c)(4)

Product Code: LBS, MRR, CHH, CDT

Dated: April 12, 2011

Received: April 14, 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 class II (Special Controls), 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). 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.

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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,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

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

Enclosure

Indications for Use

510(k) Number (if known): K111036

Device Name: EasyRA High Density Lipoproteins (HDL) Cholesterol Reagent
Indications For Use: The EasyRA HDL Cholesterol reagent is intended for the quantitative determination of High Density Lipoprotein Cholesterol in human serum and plasma on the Medica EasyRA Chemistry Analyzer. The Medica EasyRA HDL-Cholesterol reagent can assist in the diagnosis and treatment of patients at risk of developing coronary heart disease.
For *in vitro* diagnostic use only.

Device Name: EasyRA Low Density Lipoproteins (LDL) cholesterol Reagent
Indications For Use: The EasyRA LDL Cholesterol reagent is intended for the quantitative determination of Low Density Lipoprotein Cholesterol in human serum and plasma, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. The LDL Cholesterol measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
For *in vitro* diagnostic use only.

Device Name: EasyRA Cholesterol (CHOL) Reagent
Indications For Use: The EasyRA CHOL reagent is intended for the quantitative determination of total cholesterol in human serum and plasma, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Total cholesterol measurements are used to screen for elevated cholesterol as a risk factor in coronary artery disease.
For *in vitro* diagnostic use only.

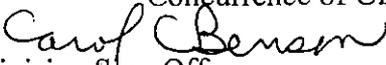
Device Name: EasyRA Triglycerides (TRIG) Reagent
Indications For Use: The EasyRA TRIG reagent is intended for the quantitative measurement of triglycerides in human serum and plasma, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism and various endocrine disorders.
For *in vitro* diagnostic use only.

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

510(k) K111036

Evaluation and Safety

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