



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

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

Re: k101088
Trade Name: EasyRA Albumin Reagent, EasyRA Calcium Reagent,
Easy RA Magnesium Reagent, Easy RA Inorganic Phosphorus Reagent
Regulation Number: 21 CFR §862.1035
Regulation Name: Albumin Test System
Regulatory Class: Class II
Product Codes: CIX, CJY, JGJ, CEO
Dated: March 30, 2011
Received: March 31, 2011

APR - 1 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.

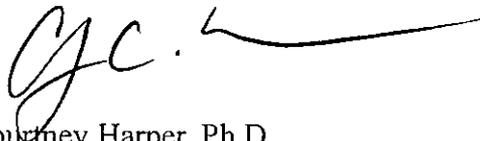
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), 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 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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

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

Courtney 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): _____

Device Name: EasyRA Albumin Reagent
Indications For Use: The EasyRA albumin reagent is intended for the quantitative determination of Albumin (ALB) in human serum **and plasma**, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.
For *in vitro* diagnostic use only.

Device Name: EasyRA Calcium Reagent
Indications For Use: The EasyRA total calcium reagent is intended for the quantitative measurement of Total Calcium (Ca) in human serum **and plasma**, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.
For *in vitro* diagnostic use only.

Device Name: EasyRA Magnesium Reagent
Indications For Use: The EasyRA magnesium reagent is intended for the quantitative measurement of Magnesium (Mg) in human serum **and plasma**, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Magnesium measurements are used in the diagnosis and treatment of: Hypermagnesemia occurring during renal failure, acute diabetic acidosis, dehydration or in Addison's disease. Hypomagnesemia observed in cases of chronic alcoholism, malabsorption, acute pancreatitis and kidney disorders.

Device Name: EasyRA inorganic phosphorous Reagent
Indications For Use: This reagent is intended for the quantitative measurement of Inorganic Phosphorous (PHOS) in human serum **and plasma**. Phosphorus measurements are used in the diagnosis and treatment of parathyroid gland, kidney diseases, and vitamin D imbalance.

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) K101088

Evaluation and Safety

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