DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

MAY 2 0 2011

Re: k101090
Trade Name: EasyRA Alkaline Phosphatase Reagent, EasyRA Aspartate Aminotransferase Reagent, EasyRA Amylase Reagent
Regulation Number: 21 CFR § 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Code: CJE, CIT, JFJ
Dated: May 11, 2011
Received: May 16, 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,

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

Indication for Use

510(k) Number (if known): k101090

Device Name:	EasyRA Alkaline phosphatase Reagent
Indication For Use:	The EasyRA Alkaline phosphatase (ALP) reagent is intended for the quantitative determination of alkaline phosphatase in human serum and plasma, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Measurement of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid and intestinal diseases. For *in vitro* diagnostic use only.
Device Name:	EasyRA Aspartate Aminotransferase Reagent
Indication For Use:	The EasyRA Aspartate Aminotranferase (AST) reagent is intended for the quantitative determination of the enzyme Aspartate Aminotranferase in human serum and plasma, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Measurement of alkaline phosphatase measurements are used in the diagnosis and treatment of certain types of liver and heart diseases. For *in vitro* diagnostic use only.
Device Name:	EasyRA Amylase Reagent
Indication For Use:	The EasyRA Amylase (AMY) reagent is intended for the quantitative determination of amylase in human serum and plasmà, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. a-Amylase in serum/plasma is used for the diagnosis and treatment of pancreatitis (inflammation of the pancreas) and other pancreatic disorders. For *in vitro* diagnostic use only.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) K101090