DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

DEC 10 2008

Re: k080810
Trade/Device Name: EasyRA Bilirubin-Direct Reagent, EasyRA Bilirubin-Total Reagent, EasyRA Phosphorus-Inorganic Reagent, EasyRA Iron Reagent, EasyRA Magnesium Reagent
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) Test System
Regulatory Class: Class II
Product Code: CIG, CEO, JMO, JGJ
Dated: December 5, 2008
Received: December 9, 2008

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); 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.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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): K080810

Device Name:	EasyRA Bilirubin-Direct Reagent
Indication For Use:	The EasyRA DBIL Reagent is for the *in vitro* measurement of Direct Bilirubin in serum specimens of adults on the Medica EasyRA analyzer. Bilirubin measurements are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.
Device Name:	EasyRA Bilirubin-Total Reagent
Indications For Use:	The EasyRA TBIL Reagent is for the *in vitro* measurement of Total Bilirubin in serum specimens of adults on the Medica EasyRA analyzer. Bilirubin measurements are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.
Device Name:	EasyRA Phosphorus Reagent
Indications For Use:	The EasyRA Phosphorus Reagent is for the *in vitro* measurement of phosphorus in serum on the Medica EasyRA analyzer. Phosphorus measurements are used in the diagnosis and treatment of parathyroid gland, kidney diseases, and vitamin D imbalance.
Device Name:	EasyRA Iron Reagent
Indications For Use:	The EasyRA Iron Reagent is for the *in vitro* measurement of iron in serum on the Medica EasyRA analyzer. Iron measurements are used in the diagnosis and treatment of iron deficiency anemia, hemochromatosis, and chronic renal disease.
Device Name:	EasyRA Magnesium Reagent
Indications For Use:	The EasyRA Magnesium Reagent is for the *in vitro* measurement of phosphorus in serum on the Medica EasyRA analyzer. Magnesium measurements are used in the diagnosis and treatment of: Hypermagnesemia occuring 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.

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)

Carol C. Benson

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

510(k) K080810