



June 11, 2018

Medica Corp.
Photios Makris
Director, QA/RA
5 Oak Park Drive
Bedford, MA 01730

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, JIY, JGJ

Dated: December 5, 2008

Received: December 9, 2008

Dear Photios Makris:

This letter corrects our substantially equivalent letter of December 10, 2008.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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 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.

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)

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

510(k) K080810