DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

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

MAY 14 2012

Re: k120497
Trade/Device Name: EasyRA HbA1c Reagent Kit, HbA1c Calibrator Kit, HbA1c QC materials
Regulation Number: 21CFR 864.7470
Regulation Name: HbA1c test system
Regulatory Class: Class II
Product Code: LCP, JIT, JJX
Dated: May 4, 2012
Received: May 7, 2012

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.

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,

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

Enclosure

Attachment J

Indications for Use

510(k) Number (if known): K120497

Device Name: EasyRA HbA1c Reagent

Indications For Use: The EasyRA HbA1c Reagent kit is intended for use in the quantitative in-vitro diagnostic determination of hemoglobin A1c (HbA1c) in human whole blood using the EasyRA clinical chemistry analyzer. HbA1c measurements are used for the monitoring of long term blood glucose control in diabetic patients.

Device Name: EasyCAL HbA1c Calibrator

Indications For Use: The EasyCAL HbA1c calibrator is used for calibrating the HbA1c on the EasyRA clinical chemistry analyzer when used in conjunction with EasyRA HbA1c Reagent. The HbA1c calibrator is used to establish points of reference that are used in the determination of values in the measurement of HbA1c in human whole blood.

Device Name: EasyQC HbA1c Quality Control Material

Indications For Use: The EasyQC HbA1c QC Materials are intended to use as quality control material for the HbA1c immunoturbidimetric assay, using EasyRA HbA1c Reagent and EasyCAL HbA1c calibrator on the EasyRA clinical chemistry analyzer.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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
Evaluation and Safety

510(k) K120497