



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

NOV 17 2008

Re: k080823

Trade/Device Name: EasyRA Amylase Reagent, EasyRA Blood Urea Nitrogen (Bun) Reagent, EasyRA Glucose-Hexokinase Reagent, EasyRA Triglyceride Reagent, EasyRA Uric Acid Reagent
Regulation Number: 21 CFR 862.1070
Regulation Name: Amylase Test System
Regulatory Class: II
Product Code: JFJ, CDQ, CFR, CDT, KNK
Dated: November 03, 2008
Received: November 04, 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).

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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.

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): K080823

Device Name: EasyRA Amylase Reagent
Indications For Use: The EasyRA amylase Reagent (AMY) is for the measurement of a-Amylase in serum using the "EasyRA chemistry analyzer". Amylase measurements are used for the diagnosis and treatment of pancreatitis (inflammation of the pancreas) and other pancreatic disorders. For *in vitro* diagnostic use only.

Device Name: EasyRA Blood Urea Nitrogen Reagent
Indications For Use: The EasyRA Blood Urea Nitrogen (BUN) Reagent is for the measurement of urea in serum using the "EasyRA chemistry analyzer". Urea measurements in serum are used for the diagnosis and treatment of certain renal and metabolic diseases. For *in vitro* diagnostic use only.

Device Name: EasyRA Glucose-Hexokinase Reagent
Indications For Use: The EasyRA Glucose hexokinase (GLU-H) Reagent is for the measurement of glucose in serum using the "EasyRA chemistry analyzer". Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and pancreatic islet cell carcinoma. For *in vitro* diagnostic use only.

Device Name: EasyRA Triglyceride Reagent
Indications For Use: The EasyRA Triglyceride (TRIG) Reagent is for the measurement of triglycerides in serum using the "EasyRA chemistry analyzer". Triglyceride measurements are used in the diagnosis and treatment of diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism or various endocrine disorders. For *in vitro* diagnostic use only.

Device Name: EasyRA Uric Acid Reagent
Indications For Use: The EasyRA Uric Acid (URIC) Reagent is for the measurement of uric acid in serum using the "EasyRA chemistry analyzer". Uric Acid measurements are used in the diagnosis and treatment of renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs. 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)

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

510(k) K080823