



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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 20 2009

Re: k080874

Trade/Device Name: EasyRA Albumin Reagent, EasyRA Alkaline Phosphatase Reagent, EasyRA Aspartate Aminotransferase Reagent, EasyRA Carbon Dioxide Reagent, EasyRA Carbon Dioxide Calibrator, EasyRA Creatinine Reagent, EasyRA Creatine Kinase Reagent
Regulation Number: 21 CFR862.1035
Regulation Name: Albumin Test System
Regulatory Class: Class II
Product Code: CIX, CJE, CIT, KHS, JIT, JFY, CGS
Dated: February 11, 2009
Received: February 12, 2009

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.

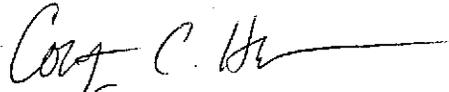
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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.

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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 (301) 594-3084. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



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

Indications for Use

510(k) Number (if known): K080874

Device Name: EasyRA Albumin Reagent
Indications For Use: The EasyRA Albumin (ALB) reagent is intended for the quantitative determination of Albumin in human serum, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

Device Name: EasyRA Alkaline Phosphatase Reagent
Indications For Use: The EasyRA Alkaline Phosphatase (ALP) reagent is intended for the quantitative determination of Alkaline Phosphatase in human serum, 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.

Device Name: EasyRA Aspartate Aminotransferase Reagent
Indications For Use: The EasyRA Aspartate Aminotransferase (AST) reagent is intended for the quantitative determination of the enzyme Aspartate Aminotransferase in human serum, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Measurement of Aspartate Aminotransferase measurements are used in the diagnosis and treatment of certain types of liver and heart diseases.

Device Name: EasyRA Carbon Dioxide Reagent
Indications For Use: The EasyRA Carbon Dioxide (CO₂) reagent is intended for the quantitative measurement of Carbon Dioxide (CO₂) in human serum. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Device Name: EasyRA Carbon Dioxide Calibrator
Indications For Use: The Carbon Dioxide calibrator establishes points of reference that are used in the determination of values in the measurement of Bicarbonate/Carbon dioxide on the EasyRA clinical chemistry analyzer when used in conjunction with Medica's CO₂ reagent.

Device Name: EasyRA Creatinine Reagent
Indications For Use: The EasyRA CREA reagent is a device intended to measure creatinine levels in serum. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis and as a calculation basis for measuring other urine analytes.

Device Name: EasyRA Creatinine Kinase Reagent
Indications For Use: The EasyRA CK reagent is a device intended to measure creatinine kinase activity in serum. Measurements of CK are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

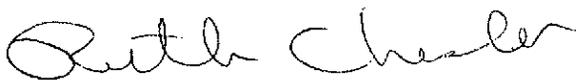
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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) K080874