



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Re: k100829
Trade Name: EasyRA Sodium Assay, EasyRA Potassium Assay,
Easy RA Chloride Assay, Easy RA Carbon Dioxide Assay
Regulation Number: 21 CFR §862.1665
Regulation Name: Sodium Test System
Regulatory Class: Class II
Product Codes: JGS, CEM, CGZ, KHS
Dated: December 16, 2010
Received: December 17, 2010

JAN 14 2011

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); 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).

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 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

Enclosure

Indications for Use

510(k) Number (if known): K100829

Device Name: EasyRA Sodium assay:

Indications For Use: The EasyRA sodium test is intended for the quantitative determination of sodium ions (Na^+) in human serum, plasma and urine using the MEDICA EasyRA Chemistry Analyzer with the ISE module option in clinical laboratories. Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
For *in vitro* diagnostic use only.

Device Name: EasyRA Potassium assay:

Indications For Use: The EasyRA potassium test is intended for the quantitative determination of potassium ions (K^+) in human serum, plasma and urine using the MEDICA EasyRA Chemistry Analyzer with the ISE module option in clinical laboratories. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
For *in vitro* diagnostic use only.

Device Name: EasyRA Chloride assay:

Indications For Use: The EasyRA chloride test is intended for the quantitative determination of chloride ions (Cl^-) in human serum, plasma and urine using the MEDICA EasyRA Chemistry Analyzer with the ISE module option in clinical laboratories. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
For *in vitro* diagnostic use only.

Device Name: EasyRA Carbon Dioxide reagent:

Indications For Use: The EasyRA carbon dioxide reagent is intended for the quantitative determination of Bicarbonate/Carbon Dioxide in human serum and plasma, using the MEDICA "EasyRA Chemistry Analyzer" in clinical laboratories. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.
For *in vitro* diagnostic use only.

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)

Carol C. Benson
Division Sign-off

Office of In Vitro Diagnostic Device
Evaluation and Safety