



Medica Corp.  
c/o Photios Makris  
Director Regulatory Affairs  
5 Oak Park Drive,  
Bedford, MA 01730

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

OCT 20 2011

Re: k112788

Trade/Device Name: EasyLyte Na/K/Ca/pH Analyzer  
Regulation Number: 21 CFR 862.1600  
Regulation Name: Potassium test system.  
Regulatory Class: II  
Product Code: CEM, CHL, JFP, JGS  
Dated: September 23, 2011  
Received: September 26, 2011

Dear Mr. 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).

Page 2 -

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  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K112788

Device Name: EasyLyte Na/K/Ca/pH Analyzer

Indications For Use: The EasyLyte Na/K/Ca/pH analyzer is used for the in-vitro diagnostic testing of Sodium(Na+), Potassium(K+), and ionized Calcium(Ca++) with pH correction in clinical laboratories by trained technicians.

### Sodium test

The sodium (Na+) assay is intended to measure sodium in serum, plasma, and whole blood. Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

### Potassium test

The potassium (K+) assay is intended to measure potassium in serum, plasma, and whole blood. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

### Calcium-ionized test

The ionized calcium (Ca++) assay is intended to measure the ionized calcium level in serum, plasma, and whole blood. Ionized calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms). Acidosis (low pH) causes increase and alkalosis (high pH) a decrease in the amount of ionized calcium.

### pH test

The sample pH assay is intended to measure the pH of the sample used in the ionized calcium assay. Measurements of pH are used to calculate the "normalized ionized calcium value" in samples with pH other than 7.40 units.

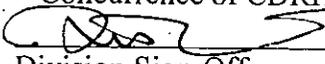
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

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) K112788  
Page 1 of 1