DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 2007

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

Re: k063376
Trade/Device Name: Easystat pH, Pco2, Po2, HTC, Na, K, Cl analyzer
Regulation Number: 21 CFR §862.1120
Regulation Name: Blood gases (Pco2, Po2) and blood pH test system.
Regulatory Class: Class II
Product Code: CHL, GKF, JGS, CEM, JFP, CGZ
Dated: May 31, 2007
Received: June 05, 2007

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.

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.

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

Indications for Use

510(k) Number (if known): K063376

Device Name: EasyStat pH, PCO2, PO2, Htc, Na^+, K^+, Ca^{++}/Cl^- Analyzer

Indications For Use:

The EasyStat pH, PCO2, PO2, Htc, Na, K, Ca/Cl analyzer is designed for clinical laboratory use, making direct measurements of pH (hydrogen ion activity), PCO_2 (partial pressure of carbon dioxide), PO_2 (partial pressure of oxygen), Htc (Hematocrit), Na^+ (sodium ions), K^+ (potassium ions), Ca^{++} (ionized calcium) and Cl^- (chloride ions) in whole blood samples from syringes or capillary tubes.

pH measurements are used in the diagnosis and treatment of diseases involving imbalance in the acid-base equilibrium in blood.

PCO2 measurements are used in the diagnosis and treatment of diseases involving imbalance in the partial pressure of carbon dioxide in blood.

PO2 measurements are used in the diagnosis and treatment of diseases conditions characterized by low or high blood oxygen levels in blood.

Hematotric (Htc) measurements are used in the diagnosis and treatment of diseases characterized by erythrocyte imbalances in whole blood.

Sodium measurements are used in the diagnosis and treatment diseases involving electrolyte imbalance.

Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Calcium (ionized) measurements are used to determine the physiologically active form of calcium in blood and establish the patient's calcium metabolism.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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

K063376