Mr. Dean Honkonen  
Director of Regulatory Affairs  
Medica Corporation  
14 DeAngelo Drive  
Bedford, MA 01730

Re: k021515  
Trade/Device Name: EasyStat pH, PCO₂, PO₂, Hct, Na⁺, K⁺, Ca²⁺ Analyzer  
Regulation Number: 21 CFR 862.1120; 21 CFR 864.5600; 21 CFR 862.1665;  
21 CFR 862.1600; 21 CFR 862.1145  
Regulation Name: Blood gases (PCO₂, PO₂) and blood Ph test system; Automated  
 hematocrit instrument; Sodium test system; Potassium test system;  
Calcium test system  
Regulatory Class: Class II  
Product Code: CHL; GKF; JGS; CEM; JFP  
Dated: May 7, 2002  
Received: May 10, 2002

Dear Mr. Honkonen:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set  
forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic  
product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): K021515

Device Name: EasyStat pH, PCO₂, PO₂, Hct, Na⁺, K⁺, Ca²⁺ Analyzer

The EasyStat analyzer is designed for clinical laboratory use, making direct measurements of pH (hydrogen ion activity), PCO₂ (partial pressure of carbon dioxide), PO₂ (partial pressure of oxygen), Hct (Hematocrit), Na⁺ (sodium), K⁺ (potassium), and Ca²⁺ (ionized calcium) on whole blood samples from syringes or capillary tubes.

This analyzer is used by laboratory trained technicians in the clinical laboratories to aide in the diagnosis and treatment of patients with electrolyte, blood gas and/or acid base disturbances. The patient results obtained from the EasyStat analyzer must be used in conjunction with the overall patient clinical condition before corrective / therapeutic action is taken.

(Division Sign-Off)
Division of Clinical Laboratory Devices

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Concurrence of CDRH, Office of Device Evaluation (ODR)

(Optional Format 3-10-98)
(Posted July 1, 1998)
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