



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**MAR 13 2009**

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

Re: k080404  
Trade/Device Name: MEDICA's EasyQC Chemistry, Levels A and B; MEDICA's Easy Electrolytes kit; MEDICA's Easy QC Chemistry and Electrolytes, Levels A and B; MEDICA's Easy Cal; MEDICA CREAT-U Cal  
Regulation Number: 21CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: Class II  
Product Code: JIT, JIX, JIY, JJR  
Dated: February 23, 2009  
Received: February 25, 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.

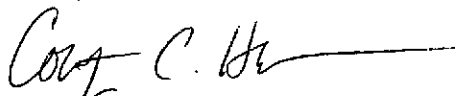
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish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

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): k080404

Device Name: EasyQC – Chemistry

Indications For Use: MEDICA's EasyQC – Chemistry, Levels A and B, is a quality control material for clinical chemistry intended for use in the MEDICA EasyRA Chemistry Analyzer to estimate test precision and to detect any potential systemic analytical deviations.

Device Name: EasyElectroLytes Kit

Indications For Use: MEDICA's EasyElectroLytes kit is a quality control material for clinical chemistry intended for use in the MEDICA EasyRA Chemistry Analyzer to estimate test precision and to detect any potential systemic analytical deviations.

Device Name: EasyQC – Chemistry & Electrolytes

Indications For Use: MEDICA's EasyQC - Chemistry and Electrolytes, Levels A and B is a quality control material for clinical chemistry intended for use in the MEDICA EasyRA Chemistry Analyzer to estimate test precision and to detect any potential systemic analytical deviations.

Device Name: EasyCal

Indications For Use: MEDICA's EasyCal - Multiconstituent Calibrator is intended for use in the MEDICA EasyRA Chemistry Analyzer to establish points of reference in the measurement of a number of analytes in human serum.

Device Name: CREA-U Cal

Indications For Use: MEDICA CREA-U Cal is intended for use in the MEDICA EasyRA Chemistry Analyzer to establish points of reference in the measurement of Creatinine in urine.

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)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

Signature Sign-Off

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Office of In Vitro Diagnostic Device  
Evaluation and Safety

K080404