DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

CLINIQA Corp.
c/o Ms. Carol Ruggiero
Director of Regulatory Affairs
774 North Twin Oaks Valley Road
San Marcos, CA 92069

JUN - 2 2008

Re: k080973
Trade Name: Cliniqa Liquid QC Complete Cardiac Marker Control, Levels 1, 2, and 3, Cliniqa LiniCal Cardiac Marker Calibration Verifiers, Levels A-D, Cliniqa Liquid QC Cardiac Marker Control-Low
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I (reserved)
Product Code: JJY
Dated: April 03, 2008
Received: April 04, 2008

Dear Ms. Ruggiero:

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

510(k) Number (if known): K080973

Device Name: CLINIQA Liquid QC Complete Cardiac Marker Control, Levels 1, 2, and 3

Indications For Use:
CLINIQA® Liquid QC™ Complete Cardiac Marker Control Levels 1, 2, and 3 is intended for use as an assayed quality control material for cardiac markers listed in the product insert. CLINIQA Liquid QC Complete Cardiac Marker Control is not intended for use as a standard.

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Device Name: CLINIQA LiniCAL Cardiac Marker Calibration Verifiers, Levels A-D

Indications For Use:
LiniCAL Cardiac Marker Calibration Verifiers are intended for use in the clinical laboratory to verify calibration and/or assess linearity of the analyzers listed in the product insert. Four assayed levels of analytes listed in the product inert are provided to allow monitoring of the
reportable range.

Device Name: CLINIQA Liquid QC Cardiac Marker Control - Low

Indications For Use:
CLINIQA Liquid QC Cardiac Marker Controls, Low is intended for use as an assayed quality control material for cardiac markers listed in the product insert. CLINIQA Liquid QC Complete Cardiac Marker Control is not intended for use as a standard.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Carol C Benson

...on Sign-Off

...ce of In Vitro Diagnostic Device
...luation and Safety

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

K080973