



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

APR 21 2009

Ms. Dawn Gast  
Quality Manager  
CLINIQA Corporation  
288 Distribution Street  
San Marcos, CA 92078

Re: k083554  
Trade name: CLINIQA® Liquid QC™ Immunoassay Control Level 1, 2 and 3  
Regulation Number: 21 CFR 862.1600  
Regulation Name: Quality control material (assayed and unassayed)  
Regulatory Class: Class I, reserved  
Product Code: JJY  
Dated: April 9, 2009  
Received: April 13, 2009

Dear Ms. Gast:

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.

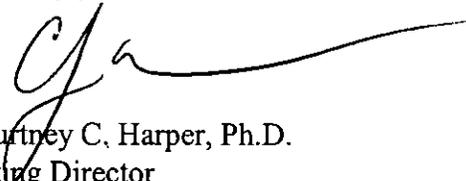
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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). 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 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 (240) 276-0450. 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 (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 <http://www.fda.gov/cdrh/industry/support/index.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

Enclosure

## Indications for Use

510(k) Number (if known): k083554

Device Name: CLINIQA<sup>®</sup> LiquidQC<sup>™</sup> Immunoassay Control Level 1, 2, and 3

### Indications For Use:

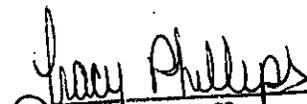
CLINIQA<sup>®</sup> Liquid QC<sup>™</sup> ImmunoAssay Controls, Levels 1, 2, & 3 are assayed, liquid, quality control products which may be used to evaluate the performance of clinical methods for immunoassay analytes listed in the product insert.

Prescription Use  (Part 21  
CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_ (Part 21  
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)

  
\_\_\_\_\_  
Tracy Phillips  
Sign-Off

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Office of In Vitro Diagnostic Device  
Regulation and Safety

k083554