



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

CLINIQA CORPORATION
c/o MS. DAWN GAST
DIRECTOR, QUALITY AND REGULATORY AFFAIRS
288 DISTRIBUTION STREET
SAN MARCOS CA 92078

May 31, 2013

Re: K120900

Trade/Device Name: Cliniqa i-STAT PT Control Level 1
Cliniqa i-STAT PT Control Level 2
Cliniqa i-STAT ACT Control Level 1
Cliniqa i-STAT ACT Control Level 2

Regulation Number: 21 CFR 864.5425

Regulation Name: Multipurpose system for in vitro coagulation studies

Regulatory Class: II

Product Code: GGN

Dated: April 29, 2013

Received: April 30, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.

Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k120900

Device Name: **Cliniqa i-STAT PT Control Level 1**

Cliniqa i-STAT PT Control Level 2

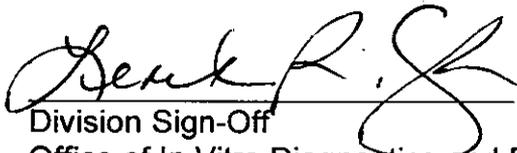
Indications For Use:

The i-STAT PT Control Level 1 (normal) and PT Control Level 2 (abnormal) are used for quality control of i-STAT PT cartridges on i-STAT handheld and wireless systems.

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 Diagnostics and Radiological Health
(OIR)



Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K120900

Indications for Use Form

510(k) Number (if known): k120900

Device Name:

Cliniqa i-STAT ACT Control Level 1

Cliniqa i-STAT ACT Control Level 2

Indications For Use:

The i-STAT ACT Control Level 1 (normal) and ACT Control Level 2 (abnormal) are used for quality control of i-STAT ACT cartridges on i-STAT handheld and wireless systems.

Prescription Use 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)

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