K121237

MAY 18 2012

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Cliniqa Corporation
288 Distribution Street
San Marcos, CA 92078
USA

Device Name

Proprietary name: Cliniqa Beta HCG Control Level 1,2,3
Common name: Quality Control Material (Assayed and Unassayed)
Classification: Class I, Reserved
Product Code: JJX

Proprietary name: Cliniqa Beta HCG Calibration Verification Control Levels 1, 2, 3
Common name: Quality Control Material (Assayed and Unassayed)
Classification: Class I, Reserved
Product Code: JJX

Predicate device

CLINIQA Liquid QC hCG Control, Levels 1, 2, 3 (k022232)

Device Description

Cliniqa Beta HCG Control Level 1, 2, 3

CLINIQA Beta HCG Control is prepared from human serum and purified human antigens. Preservatives and stabilizers have been added to maintain product integrity. CLINIQA Beta HCG Control a ready-to-use liquid control requiring no reconstitution or frozen storage.

Cliniqa Beta HCG Calibration Verification Control Levels 1,2,3

CLINIQA Beta HCG Calibration Verification Control is prepared from human serum and purified human antigens. Preservatives and stabilizers have been added to maintain product integrity. CLINIQA Beta HCG Calibration Verification Control a ready-to-use liquid control requiring no reconstitution or frozen storage.

Intended use

Cliniqa Beta HCG Control Level 1, Cliniqa Beta HCG Control Level 2, Cliniqa Beta HCG Control Level 3, are assayed quality control materials used to monitor the precision of Beta HCG assays

Cliniqa Beta HCG Calibration Verification Controls, Levels 1, 2, and 3 are assayed quality control materials used to monitor the precision of Beta HCG assays.

Comparison Table

Item	**DEVICE:** Cliniqa Beta HCG Control Level 1,2,3 Cliniqa Beta HCG Calibration Verification Controls, Level 1,2,3.	**PREDICATE (k022232)** Cliniqa LiquidQC hCG Control Level 1, Cliniqa LiquidQC hCG Control Level 2, Cliniqa LiquidQC hCG Control Level 3,
Intended Use:	Cliniqa Beta HCG Control Level 1, Cliniqa Beta HCG Control Level 2, Cliniqa Beta HCG Control Level 3, are assayed quality control materials used to monitor the precision of Beta HCG assays Cliniqa Beta HCG Calibration Verification Controls, Levels 1, 2, and 3 are assayed quality control materials used to monitor the precision of Beta HCG assays.	CLINIQA LiquidQC Control is intended for use as an assayed quality control material for quantitative Human Chorionic Gonadotropin analysis. CLINIQA LiquidQC Control is intended for use as an assayed quality control material for quantitative Human Chorionic Gonadotropin analysis.
Matrix	Human serum with added buffer, stabilizers, and purified human hormones.	Human plasma and human hormones. Preservatives, stabilizers, and sodium azide have been added.
Form	Liquid	Liquid
Open Vial Stability	30 days	30 days
Limitations	Not Applicable	Contains Sodium Azide
Caution	Human Source Material	Human Source Material
Values	Specific for each lot	Specific for each lot
Stability	Opened: 30 days at 2-8°C Shelf Life: 3 years at 2-8°C	Opened: 30 days at 2-8°C Shelf Life: 3 years at 2-8°C

Performance Characteristics

The Cliniqa Beta HCG Control Level 1,2,3 and the Cliniqa Beta HCG Calibration Verification Controls, Levels 1, 2, 3 was evaluated for value assignment and stability. See the following sections for details.

Traceability

Traceability is dependent on the manufacturer of the reagents used for value assignment. Calibration of the Roche Elecsys HCG plus Beta reagent is standardized against the 4th International Standard for Chorionic Gonadotropin from the National Institute of Biological Standards and Control (NIBSC) code 75/589.

Value Assignment

The Mean and Expected Range for each method shall be presented in each lot-specific insert of Cliniqa Beta HCG Controls and Calibration Verification Controls. The indicated values shall be derived from analysis of vials representative of the entire lot. The raw data obtained for each method shall be averaged to obtain the Mean. The Expected Range of the Mean shall be determined by combining estimates of assay variance as determined by participating laboratory data and other currently available studies.

The Expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation. The indicated Mean and Expected Range of the Mean is provided to serve only as a guide in assessing the performance of test method in laboratories.

Assignment of values shall be performed using the reagents, calibrators, and controls available at the time of assay by the manufacturer.

Stability

Real-time and accelerated stability tests were conducted to establish the shelf-life and open-vial claims.

Shelf Life of the Cliniqa Beta HCG Control Level 1,2,3 is 3 years at 2-8°C
Shelf Life of the Cliniqa Beta HCG Calibration Verification Controls, Levels 1, 2, 3 is 3 years at 2-8°C.

Open-Vial Stability
Real-time testing was performed and the data support the package insert claim that the Cliniqa Beta HCG Control Level 1, 2, 3 is stable up 30 days at 2-8°C once opened.

Open-Vial Stability
Real-time testing was performed and the data support the package insert claim that the Cliniqa Beta HCG Calibration Verification Control Level 1, 2, 3 is stable up 30 days at 2-8°C once opened.

Shelf-Life Stability:
The accelerated stability testing performed at 45°C and 37°C supports an initial shelf-life claim of 3.6 years at 2-8°C. For the Cliniqa Beta HCG Control Level 1, 2, 3 Real-time testing at 2-8°C is on-going to support a claim of 3 years.

The accelerated stability testing performed at 45°C and 37°C supports an initial shelf-life claim of3.6 years at 2-8°C. For the Cliniqa Beta HCG Calibration Verification Control Level 1, 2, 3 Real-time testing at 2-8°C is on-going to support a claim of 3 years.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Cliniqa Corporation
c/o Dawn Gast
288 Distribution Street
San Marcos. CA 92078

MAY 18 2012

Re: k121237
Trade Name: Cliniqa Beta HCG Control Level 1, 2, 3
Cliniqa Beta HCG Calibration Verification Controls Levels 1, 2, 3
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: April 23, 2012
Received: April 24, 2012

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).

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 (301) 796-5450. 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 (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121237

Device Name:

Cliniqa Beta HCG Control Level 1,2 ,3

Cliniqa Beta HCG Calibration Verification Controls Levels 1, 2, 3

Indications for Use:

Cliniqa Beta HCG Controls, Levels 1, 2, and 3 and Cliniqa Beta HCG Calibration Verification Controls, Levels 1, 2, and 3 are assayed quality control materials used to monitor the precision of Beta HCG assays.

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

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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