DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 21, 2016

QUANTIMETRIX CORPORATION
KALYNA SNYLYK
DIRECTOR, REGULATORY AFFAIRS/QUALITY ASSURANCE
2005 MANHATTAN BEACH BLVD
REDONDO BEACH, CA 90278-1205, US

Re: K152117
Trade/Device Name: Dropper® hsCRP High Sensitivity CRP Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: February 19, 2016
Received: February 22, 2016

Dear Kalyna Snylyk:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k152117

Device Name
Dropper hsCRP High Sensitivity CRP Control

Indications for Use *(Describe)*

The Quantimetrix Dropper hsCRP High Sensivity CRP Control is intended for the quality control of laboratory testing procedures of high sensitivity C-Reactive protein (CRP). It is intended for professional in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k)

510(k) Summary

Dropper® hsCRP High Sensitivity CRP Control

Submitter:

Quantimetrix Corporation
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278

Contact person:

Kalyna Snylyk
Director Regulatory Affairs and Quality Assurance
Telephone: (310) 536-0006
Fax: (310) 536-9977

Date Summary prepared:

April 15, 2016

Regulatory Information:

Product Trade name:	Dropper® hsCRP High Sensitivity CRP Control
Common name:	Assayed CRP Control
Review Panel:	Clinical Chemistry
Classifications:	Class I, reserved
Product code:	JJX
Regulation number:	21 CFR 862.1660

Device to which substantial equivalence is claimed

Liquicheck Cardiac Markers Plus Control LT
Bio-Rad Laboratories
Irvine, CA 92618-2017

510(k) number K123663

Indications For Use

The Quantimetrix Dropper® hsCRP High Sensitivity CRP Control is intended for the quality control of laboratory testing procedures of high sensitivity C-Reactive protein (CRP). It is intended for prescription in vitro diagnostic use only.

Description of Device

The Dropper® hsCRP Control is a ready-to-use liquid control that does not require reconstitution nor frozen storage. The product is supplied in three clinically significant levels filled to 1mL in convenient plastic dropper bottles. The controls are formulated in a human serum derived matrix fortified with preservatives and stabilizers to maintain product integrity and inhibit microbial growth. Each control level is formulated with human CRP antigen to clinically significant targets that are ideal to monitor high sensitivity CRP test methods.

The blood donor units comprising the serum pool serum are screened for HBs and HBc antigen, HCV, HIV1, and HIV2, and found to be nonreactive by US FDA accepted methods.

Value Assignment

The value assignment testing is performed by submitting samples of a specific lot to be tested to multiple laboratories and Quantimetrix laboratory to be tested across different analyzer platforms. Expected values are established from interlaboratory and intralaboratory data using instrument manufacturer's reagents. Data derived from replicate analyses and are specific to each lot of product. Individual laboratory means should fall within the ranges listed. Value assignment ranges are established based on evaluation of data, calculating a mean value and applying a +/- 3SD range around the mean value. These values should be used as a guide in evaluating the performance of test methods. Each laboratory should establish its own ranges and specifications for the methods used to measure hsCRP. Variations from the published insert values may occur due to laboratory technique, changes in instrumentation and reagents, or to manufacturer's test methods.

Intended use

The Quantimetrix Dropper® hsCRP Control is an assayed quality control material used to monitor the performance of high sensitivity C-Reactive Protein (CRP) test methods.

Comparison of the New Device with the Predicate Device

The Dropper hsCRP Control claims substantial equivalence to the Liquicheck Cardiac markers Plus LT Control currently in commercial distribution (K123663). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1: Similarities and Differences between new and predicate device:

Characteristics	Dropper hsCRP High Sensitivity Control (New device)	Liquicheck Cardiac Markers Plus Control LT (Predicate Device K123663)
Similarities		
Intended Use	Same	The product is intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.
Form	Same	Liquid
Matrix	Same	Human Serum
Level	**3 Level Control**	**3 Level Control**
Differences		
Storage Unopened (Shelf Life)	**At 2-8°C until the expiration date (36 months)**	**At – 20 to -50° C until the expiration date (3 years)**
Open Vial	**90 days at 2-8°C and 30 days at room temp (18-25°C)**	**20 days at 2-8°C for most analytes (Thawed and Opened)**
Form	Ready-to-Use Liquid	Frozen Liquid
Analyte(s)	**<u>Single Analyte</u> –** **C-Reactive Protein (CRP)**	**<u>Multi Analyte</u> –** **Troponin I** **Creatine Kinase, Total (CK Total)** **CK-MB Isoenzyme** **Digitoxin** **C-Reactive Protein (CRP)** **Myoglobin** **N-terminal pro-Brain natriuretic Peptide (NT-proBNP)**

Fill Volume	1mL	2.5 mL
Storage Condition	Refrigerated (2-8° C) until expiration date	Frozen (-20° to -70°C) until expiration date

Statement of Supporting Data:

Accelerated stability studies were conducted to establish the open and unopened stability claims.
Accelerated stability studies were conducted to establish the shelf-life stability claim.
Acceptance criteria were met to support the product claims as follows:

Open vial Stability:	90 days at 2 to 8°C
Open vial stability:	30 days at room temp. (18-25° C)
Shelf life Stability:	36 months at 2 to 8°C

Real time stability studies are ongoing and performed for every lot.

Conclusion:

Based on the performance characteristics indicated above, the Dropper hsCRP High Sensitivity CRP Control is substantially equivalent to the predicate device Liquicheck Cardiac Markers Plus Control LT reference 510(k) K123663

All supporting data is retained on file at Quantimetrix Corporation.