

NOV 23 1999

K993723

## 510K Summary

**Prepared:** October 26, 1999

**Submitted by:**

**Establishment Address:** Quantimetrix Corporation  
2005 Manhattan Beach Boulevard  
Redondo Beach CA 90278  
Phone: 310/536-0006 FAX: 310/536-9977

**Establishment Registration Number:** 2020715

**Contact Person:** Evy K. Johnson, Director Technical Services & OEM

**Proprietary Name:** Cardiasure Assayed Cardiac Markers Control

**Common Name:** Cardiac Markers Control

**Classification Name:** Enzyme Controls (assayed and unassayed) 75 JJT

### **Substantial Equivalence:**

The Quantimetrix Cardiasure Control is supplied liquid in three levels and consists of a human serum matrix containing preservatives to which reagent grade chemicals and human source antigens and enzymes have been added at different concentrations to achieve the three levels. Assayed values are determined from interlaboratory data.

The Quantimetrix controls are substantially equivalent to other such controls in general use, such as the **Liquichek™ Cardiac Markers Control** sold by BioRad Laboratories Inc., which is supplied liquid in three levels as a human serum matrix with human/non-human source constituents and pure chemicals added by the manufacturer.

### **Description:**

Cardiasure Assayed Controls are supplied in three levels, 3 x 3 mL each level per box and as a Tri-Level pack: 3 vials at 3 mL of each level; the controls are supplied as a ready-to-use frozen liquid, requiring no reconstitution or dilution. They are prepared in a human serum matrix fortified to target levels with human source material and reagent grade chemicals added at different concentrations to achieve the three levels. Sodium Azide has been added as preservative to inhibit microbial growth.

### **Intended Use:**

The Quantimetrix Cardiasure Assayed Controls are intended for use as quality control materials to assess the accuracy and precision of assay procedures for the analytes included in the control.

### **Technological Characteristics Compared to Predicate Devices:**

The Quantimetrix control product uses a matrix and constituent formulation similar to the equivalent predicate device listed above: human serum matrix fortified with human source material, reagent grade chemicals and a preservative. The Quantimetrix Control also has similar storage and stability requirements as the predicate device.

**Performance Characteristics:**

The closed vial stability claim made for this product is 3 years when stored at -10 to -20° C, based on accelerated stability studies.<sup>2</sup> The Cardiasure control was stored at 2 to 8°C for over 60 days to simulate 3 years storage at -10 to -20°C. An increase or decrease of >10% of analyte recovery compared to the initial test value ± the highest allowable instrument/reagent imprecision was used as the analyte failure criterion for determining shelf life. Real time stability testing is ongoing on multiple lots of product.

The closed and opened vial stability claim for this product when stored at 2 - 8° C is 30 days. The Cardiasure Control was stored at 2 - 8° C and the recovery (vs. day 0) was measured in regular intervals up to 35 days for open vial and up to 64 days for closed vial. The product was deemed stable if it met the above recovery criteria.

All lots passed the 30 day refrigerated stability for opened/closed vials (with the exception of Tn-I which has a 14 day stability claim).

Multiple lots of product were tested with no significant difference in performance or stability.

The predicate device, Liquichek™ Cardiac Markers Control, claims a 2 year shelf life for storage at -10°C to -20°C and a 20 day opened/closed vial stability for refrigerated (2-8°C) storage, with exception of Tn-I and T which have are claimed to be stable for 10 days .

**Assayed Values**

Assay values were established from interlaboratory data using instrument manufacturers' reagents. Mean values and expected ranges for the listed lots of controls were calculated from multiple instruments and reagent lots available at the time of assay.

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<sup>2</sup> L. Kennon, Stability Prediction Model, Journal of Pharmaceutical Sciences 53:7, 815-818, 1964.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

NOV 23 1999

Ms. Evy K. Johnson  
Director, Technical Services & OEM  
Quantimetrix Corporation  
2005 Manhattan Beach Boulevard  
Redondo Beach, California 90278-1205

Re: K993723  
Trade Name: Cardiasure  
Regulatory Class: I  
Product Code: JJT  
Dated: October 26, 1999  
Received: November 3, 1999

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

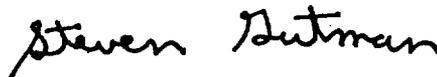
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K993723

Device Name: Cardiasure Cardiac Markers Control

Indications For Use:

**Indications for Use**

The Quantimetrix Cardiasure Control is to be used as a quality control material to assess the accuracy and precision of laboratory test methods used to measure the specific serum analytes contained in the control material in order to validate the measurement of these analytes in patient samples.

Quality Control materials that have known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intra- and interlaboratory parameters for accuracy and precision of the test method.

Three levels of control are provided to allow the performance of the test methods to be monitored within the clinically significant ranges.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K993723

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use