510K Summary

K973894

Prepared: October 6, 1997

OCT 29 1997

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: Immusure Assayed Chemistry Control

Common Name: Immunoassay / TDM Control

Classification Name: Multi Analyte Controls, All Kinds (assayed and unassayed) 75 JJY

Substantial Equivalence:
The Quantimetrix Immusure Immunoassay /TDM Control is substantially equivalent to Tri-Point™ Brand Liquimmune® Liquid Assayed Immunoassay Controls manufactured by Medical Analysis Systems, Inc., and to Dade® Immunoassay Controls Comprehensive Tri-Level manufactured by Dade International, Inc., and to Liquichek™ Immunoassay Plus Control manufactured by Bio-Rad Laboratories.

Description:
Immusure Assayed Immunoassay / TDM Controls are supplied in three levels, 6 x 5 mL each level per box and as a Tri-Level pack 6 vials 2 x 5 mL each level, as a ready-to-use liquid, requiring no reconstitution or dilution. They are prepared in a human serum matrix fortified to target levels with human and nonhuman source material and reagent grade chemicals added at different concentrations to achieve the three levels. Bacteriostatic and antifungal agents have been added as preservatives to inhibit microbial growth.

Intended Use:
The Quantimetrix Immusure Assayed Immunoassay / TDM 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 employs a similar matrix and constituent formulation to the equivalent predicate devices listed above: human serum matrix fortified with human and nonhuman source material reagent grade chemicals, bacteriostatic and antifungal agents as preservatives. The Quantimetrix Control also has similar storage and stability requirements as the equivalent devices.

Performance Characteristics:
The closed vial stability claim made for this product is 3 years when stored at -10 to -20 C with certain analyte limitations. The overall shelf life of the Immusure control was extrapolated from accelerated stability models using elevated temperature storage to simulate real time stability.[1] The Immusure control was stored at 2 - 8 C 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 or to the highest allowable instrument/reagent imprecision, whichever was greater, was used as the analyte failure criteria for determining shelf life. Folate may show a gradual decrease over time. Real time stability testing is ongoing on multiple lots of product.

[1] L. Kennon, Stability Prediction Model, Journal of Pharmaceutical Sciences 53:7, 815-818, 1964.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 29 1997

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

Re: K973894
Immusure
Regulatory Class: I
Product Code: JJY, DIF
Dated: October 6, 1997
Received: October 14, 1997

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 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.

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/dsmamain.html".

Sincerely yours,

Steven Gutman

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

3. **Indications for Use**

The Quantimetrix Immusure Immunoassay/TDM Control is to be used as a quality control material to assess the accuracy and precision of laboratory test methods used to measure the serum analytes and therapeutic drugs contained in the control. It is intended to validate the measurement of these analytes and drugs in patient serum samples.

Quality Control materials having known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method. CLIA regulation 493.1202(C)(4) requires labs to perform and document control procedures for each day of testing.

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

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973894