

# KAMIYA BIOMEDICAL COMPANY

910 Industry Drive, Seattle, WA 98188 USA

TEL: (206) 575-8068

FAX: (206) 575-8094

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: K 98 4045

Date: October 30, 1998

Submitted by: Colin Getty  
KAMIYA BIOMEDICAL COMPANY  
910 Industry Drive, Seattle WA 98188  
TEL: 206-575-8068; FAX: 206-575-8094

Product: RF Control Set

The KAMIYA RF Control is a lyophilized, human serum-based, assayed control for use as a consistent test sample of known concentration for monitoring the performance of RF immunoturbidimetric assays.

Two levels of the KAMIYA RF Control are provided. The human serum used to manufacture this product is tested and found negative for the presence of HBsAg and antibody to HCV and HIV. The assigned RF values are traceable to the WHO International Reference Preparation of Rheumatoid Arthritis Serum. This product is stable for at least 1 year (unopened) and 2 weeks (after reconstitution).

The safety and effectiveness of the KAMIYA RF Control is demonstrated by its substantial equivalence to the Sigma Immunology Control (K851202). The KAMIYA RF Control exhibits similar within run and between day precision and reaction characteristics for the analyte.



JAN 25 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Colin Getty  
Official Correspondent  
Kamiya Biomedical Company  
910 Industry Drive  
Seattle, Washington 98188

Re: K984045  
Trade Name: RF Control Set for Immunoturbidimetric Assays  
Regulatory Class: II  
Product Code: DHR  
Dated: October 30, 1998  
Received: November 13, 1998

Dear Mr. Getty:

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.

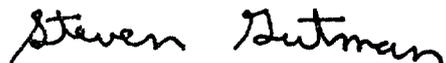
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

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

# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 984045

Device Name: RF Control Set

## Indications For Use:

As a consistent test sample of known concentration for monitoring the performance of RF immunoturbidimetric assays.

(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 K98404

Prescription Use              
(Per 21 CFR 801.109)

OR

Over-The-Counter Use           

Optional Format 1-2-96)