MAY 29 1997

K964767

510(k) Summary
Quantikine™ IVD™ β_2 microglobulin enzyme immunoassay

Date of Summary:	November 27, 1996
Company Name:	R&D Systems, Inc. 614 McKinley Place N.E. Minneapolis, MN 55413
Contact name:	Kenneth T. Edds, Ph.D. 612-379-2956, FAX 612-379-6580
Classification name:	β_2 microglobulin immunological test system
Product name:	Quantikine IVD β_2 microglobulin enzyme immunoassay
CFR section:	866.5630
Device Class:	Class II

Device to which substantial equivalence is claimed:
Pharmacia's β_2 Micro RIA currently being marketed by Pharmacia Diagnostics, Fairfield, N.J. 07006.

The product is a competitive binding enzyme immunoassay (EIA) for β_2 microglobulin.

It is intended for the quantitative determination of β_2 microglobulin concentration in human serum and urine as an aid in the diagnosis of active rheumatoid arthritis and kidney diseases.

R&D Systems' Quantikine IVD β_2-microglobulin enzyme immunoassay has an intended use that is similar to the predicate device. The technologies of the two devices are similar in that both are competitive binding based assays. They differ in the "reporter" moeity attached to assayed molecule. R&D System's assay is colorimetric and Pharmacia's is radiometric.

Nonclinical testing centered on the performance attributes of accuracy, precision and stability. In addition to demonstrating acceptable performance for the above attributes Quantikine IVD β_2-microglobulin enzyme immunoassay passed the additional acceptance criteria that all parameters met their individual specifications. Those criteria are:

1) Signal generated by standard 0 to be greater than 1.5 absorbance units

2) Signal generated by standard 5 to be less than 0.35 absorbance units

3) Curve fitting - individual replicates of Standard 1 to fit within ±15% of nominal value and the Mean value of Standard 1 to fit within ±10% of nominal value. Individual replicates and Mean values of Standards 2 -5 to fit within ± 10% of nominal value.

4) In house control and kit control values to be within the ranges quoted on the appropriate control data sheets.

5) Sensitivity to be less than 0.2 µg/mL.

6) Precision - based on 10 replicates of three in-house controls, to be typically less than 8%.

All other performance parameters were similar to the predicate device. Expiration dating has been established as 26 weeks when stored at 2-8°C and handled according to instructions for use. Opened or diluted reagents are good for up to 4 weeks when stored at 2-8°C provided that this is within the expiration date.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 29 1997

Kenneth T. Edds, Ph.D.
Regulatory Affairs
R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, Minnesota 55413

Re: K964767/S1
Trade Name: β_2 Microglobulin Immunological Test System
Regulatory Class: II
Product Code: JZG
Dated: March 24, 1997
Received: March 25, 1997

Dear Dr. Edds:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 at (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

510(k) Number: **K964767**

Device Name: Quantikine™ IVD™ β_2 Microglobulin Enzyme Immunoassay Kit

Indications for Use: The Quantikine IVD β_2-microglobulin EIA kit is intended for the quantitative determination of β_2 microglobulin concentration in human serum and urine as an aid in the diagnosis of active rheumatoid arthritis and kidney diseases.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse_____

(Optional Format 1-2-96)