

3/8/99

510(k) Summary

Submitter's Name/Address

Abbott Laboratories
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Contact Person

Mark Littlefield
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ADD Regulatory Affairs
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Date of Preparation of this Summary:

January 4, 1999

Device Trade or Proprietary Name:

RF

Device Common/Usual Name or Classification Name: Rheumatoid Factor

Classification Number/Class:

Class II

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:

K990035

Test Description:

Rheumatoid Factor is an *in vitro* diagnostic assay for the quantitative determination of rheumatoid factor in human serum or plasma. The rheumatoid factor, an autoimmune antibody, in the sample interacts with the aggregated (denatured) human gamma globulin in the reagent forming immune complexes. The immune complexes cause an increase in light scattering, measured at 340 and 700 nm, which correlates with the concentration of rheumatoid factor in the sample.

Substantial Equivalence:

The Rheumatoid Factor assay is substantially equivalent to the K-ASSAY® Rheumatoid Factor assay (K964415) on the Hitachi® 717 Analyzer.

Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are *in vitro* immunoassays.
- Both assays can be used for the quantitative determination of rheumatoid factor.
- Both assays yield similar clinical results.
- Both assays are based on the light scattering properties of immune complexes.

Differences:

- There is a difference between the assay range.
- There is a difference in the test mode.

Intended Use:

The Rheumatoid Factor assay is used for the quantitation of rheumatoid factor in human serum or plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSSET™ System. The Rheumatoid Factor assay method comparison yielded acceptable correlation with the K-ASSAY Rheumatoid Factor assay on the Hitachi 717 Analyzer. The correlation coefficient = 0.9883, slope = 1.082, and the Y-intercept = -3.168 U/mL. Precision studies were conducted using the Rheumatoid Factor assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 502 is 5.2% and Level 2/Panel 503 is 2.2%. The Rheumatoid Factor assay range is 0.76 to 413.08 U/mL. The limit of quantitation (sensitivity) of the Rheumatoid Factor assay is 2.97 U/mL. These data demonstrate

that the performance of the Rheumatoid Factor assay is substantially equivalent to the performance of the K-ASSAY Rheumatoid Factor assay on the Hitachi 717 Analyzer.

Conclusion:

The Rheumatoid Factor assay is substantially equivalent to the K-ASSAY Rheumatoid Factor assay on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.



MAR - 8 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Mark Littlefield
Section Manager, Regulatory Affairs
Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Re: K990035
Trade Name: RF
Regulatory Class: II
Product Code: DHR
Dated: January 4, 1999
Received: January 6, 1999

Dear Mr. Littlefield:

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.

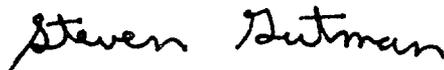
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 style with a large initial 'S'.

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): K990035

Device Name: Rheumatoid Factor

Indications For Use:

The Rheumatoid Factor assay is used for the quantitation of rheumatoid factor (antibodies to immunoglobulins) in human serum or plasma. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990035

(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-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)