

CONFIDENTIAL

K981241

MAY 1 1998

510(k) Summary**Submitter's Name/Address**

Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Contact Person

Mark Littlefield
Section Manager MS 1-8
Regulatory Affairs
(972) 518-7861
Fax (972) 753-3367

Date of Preparation of this Summary:

April 03, 1998

Device Trade or Proprietary Name:

Iron

Device Common/Usual Name or Classification Name:

Iron

Classification Number/Class:

75CFM/Class I

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: _____.

Test Description:

Iron is an *in vitro* diagnostic assay for the quantitative determination of iron in human serum. The Iron assay is a clinical chemistry assay which utilizes an acidic media to release ferric iron from the transferrin. The ferric iron is converted to the ferrous form by the action of hydroxylamine hydrochloride. The released ferrous iron reacts with FERENE[®] to produce a colored Iron-FERENE complex. The absorbance of the Iron-FERENE complex is measured at 600 nm and is proportional to the concentration of iron present in the sample. Thiourea and detergent are added to reduce copper interference and turbidity, respectively.

Substantial Equivalence:

The Iron assay is substantially equivalent to the Raichem[®] Serum Iron assay (K864819) on the Roche[®] Cobas Mira[®] Plus Automated Chemistry System.

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Both assay yield similar Performance Characteristics.

Similarities:

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of iron.
- Both assays yield similar clinical results.

Differences:

- There is a difference between the assay range.

Intended Use:

The Iron assay is used for the quantitation of iron in human serum ALCYON 300/300i Analyzer.

Performance Characteristics:

Comparative performance studies were conducted using the ALCYON™ Analyzer. The Iron assay method comparison yielded acceptable correlation with the Raichem Serum Iron assay on the Roche Cobas Mira Plus Automated Chemistry System. The correlation coefficient = 0.9835, slope = 0.929, and Y-intercept = -0.385 µg/dL. Precision studies were conducted using the Iron assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 111 is 2.7% and Level 2/Panel 112 is 5.5%. The Iron assay is linear up to 1,400 µg/dL. The limit of quantitation (sensitivity) of the Iron assay is 10 µg/dL. These data demonstrate that the performance of the Iron assay is substantially equivalent to the performance of the Raichem Serum Iron assay on the Roche Cobas Mira Plus Automated Chemistry System.

Conclusion:

The Iron assay is substantially equivalent to the Raichem Serum Iron assay on the Roche Cobas Mira Plus Automated Chemistry System as demonstrated by results obtained in the studies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 1 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K981241
Iron
Regulatory Class: I
Product Code: JIY
Dated: April 3, 1998
Received: April 6, 1998

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 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 (Pre-market 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 pre-market 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.

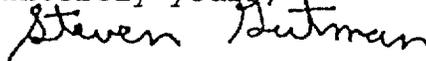
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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

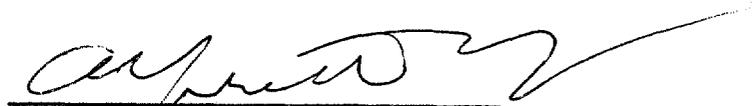
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510(k) Number (if known): _____

Device Name: Iron

Indications For Use:

The Iron assay is used for the quantitation of iron in human serum on the ALCYON 300/300i Analyzer. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981241

(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)

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