K98 1659

JUL 22 1998

510(k) Summary

Submitter's Name/Address
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Date of Preparation of this Summary: May 8, 1998

Device Trade or Proprietary Name: TIBC

Device Common/Usual Name or Classification Name: TIBC

Classification Number/Class: 75JMO/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:

Total Iron Binding Capacity (TIBC) is an *in vitro* diagnostic assay for the quantitative determination of total iron binding capacity of human serum. The TIBC assay is a clinical chemistry assay which involves a sample pretreatment followed by the analysis of TIBC with the Iron reagents. Ferric chloride saturating solution is mixed with the sample to bind all available apotransferrin binding sites with iron. Alumina adsorbent removes excess iron from the mixture. The mixture is then analyzed for total iron and the result is multiplied by the dilution factor to compensate for dilution by the saturating solution.

Substantial Equivalence:

The TIBC assay is substantially equivalent to the A-GENT® TIBC assay on the ABBOTT SPECTRUM® Series II™ System.

Both assays yield similar Performance Characteristics.

Similarities:

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

Differences:

- There is a difference in the assay range.

Intended Use:

The Total Iron Binding Capacity (TIBC) assay uses TIBC sample pretreatment in conjunction with the Iron assay for the quantitation of the total iron binding capacity of human serum.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET™ Analyzer. The TIBC assay method comparison yielded acceptable correlation with the A-GENT TIBC assay on the ABBOTT SPECTRUM Series II System. The correlation coefficient = 0.9896, slope = 0.988, and Y-intercept = 6.790 µg/dL. Precision studies were conducted using the TIBC 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 2.1% and 4.3% for Level 2/Panel 112. The Iron assay is linear up to 1778.5 µg/dL. The limit of quantitation (sensitivity) for the Iron assay is 3.8 µg/dL. The calculated TIBC values are acceptable from 11.4 µg/dL to 5335.5 µg/dL. These data demonstrate that the performance of the TIBC assay is substantially equivalent to

the performance of the A-GENT TIBC assay on the ABBOTT SPECTRUM Series II System.

Conclusion:

The TIBC assay is substantially equivalent to the A-GENT TIBC assay on the ABBOTT SPECTRUM Series II System as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 22 1998

Mark Littlefield
Section Manager, Regulatory Affairs
ABBOTT LABORATORIES
1920 Hurd Drive
Irving, TX 75038

Re: K981654
Trade Name: TIBC
Regulatory Class: I
Product Code: JMO
Dated: May 8, 1998
Received: May 11, 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 (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 requirement, 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 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 (if known): K981654

Device Name: TIBC

Indications For Use:

The Total Iron Binding Capacity (TIBC) assay uses TIBC sample pretreatment in conjunction with the Iron assay for the quantitation of the total iron binding capacity of human serum. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981654

(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)