K994115

JAN 2 8 2000

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

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.

Submitter's Name:	Robin O. Norris Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101
Date of Preparation:	December 2, 1999
Name of Product:	Total Iron Binding Capacity (IBCT) Flex® reagent cartridge
FDA Classification Name:	Iron Binding Capacity Test System
Predicate Device:	Dimension® Total Iron Binding Capacity (TIBC) Flex® reagent cartridge (K864230)

Device Description: The IBCT method for the Dimension® clinical chemistry system is a fully automated assay in which serum or plasma is mixed with a ferric iron solution, to saturate all available iron-binding sites of transferrin in the sample. Under non-acidic conditions (pH 8.6), only unbound, excess saturating iron is available to be reduced to ferrous iron by ascorbic acid and to form a blue complex with Ferene®. Subsequent addition of acid (final pH of 4.5) releases the iron bound to transferrin; this additional iron is reduced to ferrous iron by ascorbic acid and forms an increased amount of blue complex with Ferene®. The increase in absorbance upon shifting from pH 8.6 to pH 4.5, measured using a bicromatic (600,700 nm) endpoint technique, is proportional to the concentration of transferrin-bound iron, and thus to the iron binding capacity (total) of the serum or plasma sample.

Intended Use: The Total Iron Binding Capacity (IBCT) Flex® reagent cartridge is used in the Dimension® clinical chemistry system to quantitatively measure total iron binding capacity in human serum and plasma.

Comparison to Predicate Device:

Item	IBCT Flex® reagent cartridge	TIBC Flex® reagent cartridge
Sample Type	serum and plasma	serum
Methodology	Photometric measurement	Pretreatment step, followed by Photometric measurement
Detection	Bichromatic endpoint (600 and 700 nm)	Bichromatic endpoint (600 and 700 nm)

Comments on Substantial Equivalence: Split sample comparison between the IBCT Flex® reagent cartridge and TIBC Flex® reagent cartridges on the Dimension® clinical chemistry system gave a correlation coefficient of 0.971, slope of 1.14, and an intercept of –22.4 ug/dL when tested with 137 clinical patient samples ranging from 59 to 469 ug/dL TIBC.

Conclusion: The IBCT Flex® reagent cartridge is substantially equivalent in principle and performance to the TIBC Flex® reagent cartridge based on the comparison discussed above.

Robin O. Norris
Manager, Quality Assurance and Compliance
December 2, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 8 2000

Ms. Robin O. Norris
Manager, Quality Assurance and Compliance
Dade Behring, Inc.
Building 500, Mailbox 514
P.O. Box 6101
Newark, Delaware 19714-6101

Re: K994115
Trade Name: Total Iron Binding Capacity Flex® Reagent Cartridge
Regulatory Class: I reserved
Product Code: JMO
Dated: December 2, 1999
Received: December 6, 1999

Dear Ms. Norris:

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.

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" (21CFR 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,

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

Indications For Use Statement

Device Name: Total Iron Binding Capacity Flex® reagent cartridge

Indications for Use:

The Total Iron Binding Capacity (IBCT) Flex® reagent cartridge for the Dimension® clinical chemistry system is an *in vitro* diagnostic device intended to quantitatively measure total iron binding capacity in human serum and plasma. Measurements of total iron binding capacity are used in the diagnosis and treatment of iron deficiency anemia and chronic inflammatory disorders.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994115

Robin O. Norris
Manager, Quality Assurance and Compliance

December 2, 1999

(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)