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K994114

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: Dimension® IBCT Calibrator

FDA Classification Name: Calibrator

Predicate Device: Dimension® IRN/TIBC Calibrator, K863840

Device Description: The Dimension® IBCT Calibrator is a liquid protein based product. The kit consists of six vials; two at each of three levels.

Intended use: The Dimension® IBCT Calibrator is intended to be used to calibrate the Total Iron Binding Capacity (IBCT) method on the Dimension® clinical chemistry system.

Comparison to Predicate Device:

Item	Dimension® IRN/TIBC Calibrator	Dimension® IBCT Calibrator
Intended Use	Calibrator	Calibrator
Analytes	iron	human transferrin
Matrix	aqueous solution	protein based solution
Form	liquid	liquid
Volume	1.0 mL per ampule	1.0 mL per vial
Levels	3 levels	3 levels
Reference	Primary standard -- NIST Iron Standard SRM 937	Primary standard – NIST Iron Standard SRM 937

Comments on Substantial Equivalence: Both the Dimension® IRN/TIBC Calibrator and the Dimension® IBCT Calibrator are intended to be used as calibrators for total iron binding capacity methods.

Conclusion: The Dimension® IBCT Calibrator is substantially equivalent to the Dimension® IRN/TIBC Calibrator based on the comparison discussed above.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 0 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: K994114
Trade Name: Dimension® IBCT Calibrator
Regulatory Class: II
Product Code: JIS
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

K994114

Device Name: Dimension® IBCT Calibrator

Indications for Use:

The IBCT Calibrator for the Dimension® Clinical Chemistry System is a device intended to calibrate the Dimension® clinical chemistry system for total iron binding capacity (IBCT) method.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994114

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)