K061251

510(k) 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:

Lorraine Piestrak
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

MAY 3 1 2006

Date of Preparation: May 3, 2006

Name of Product: Dimension Vista™ Total Iron Binding Capacity (TIBC) Calibrator

FDA Classification Name/Product Code: Calibrator / JIS

Predicate Device: Dimension® IBCT Calibrator (K994114)

Device Description:
The Dimension Vista™ Total Iron Binding Capacity (TIBC) Calibrator is a liquid, bovine albumin based product containing human transferrin. The kit consists of 3 vials, each containing 1.0 mL.

Intended use:
The TIBC Calibrator is an in vitro diagnostic product for the calibration of the Total Iron Binding Capacity (TIBC) method on the Dimension Vista™ system.

Comparison to Predicate Device:

	Dimension Vista™ TIBC Calibrator	Dimension® IBCT Calibrator (predicate)
Intended Use	Calibrator	Calibrator
Analyte	human transferrin	human transferrin
Matrix	bovine albumin	bovine albumin
Form	liquid	liquid
Volume	1 mL per vial	1 mL per vial
Levels	1 level (Zero level is system water on board the instrument)	3 levels (Zero level provided)
Reference	Primary standard NIST Iron Standard SRM 937	Primary standard NIST Iron Standard SRM 937

Comments on Substantial Equivalence:
Both the proposed Dade Behring Dimension Vista™ Total Iron Binding Capacity (TIBC) Calibrator and the existing Dimension® IBCT calibrator are *in vitro* diagnostic products intended for calibrating Total Iron Binding Capacity assays.

Conclusion:

Conclusion:
The Dimension Vista™ Total Iron Binding Capacity (TIBC) Calibrator is substantially equivalent to the Dimension® IBCT Calibrator based on the comparison discussed above.

Lorraine Piestrak
Regulatory Affairs and Compliance Manager
May 3, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 3 1 2006

Ms. Lorraine H. Piestrak
Regulatory Affairs & Compliance Manger
Dade Behring, Inc.
PO Box 6101, M/S 514
Newark, DE 19714-6101

Re: k061251
Trade/Device Name: Dimension Vista™ Total Iron Binding Capacity (TIBC) Calibrator
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIS
Dated: May 3, 3006
Received: May 4, 2006

Dear Ms. Piestrak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

K061251

Device Name: Dimension Vista™ Total Iron Binding Capacity (TIBC) Calibrator

Indications for Use:

The Dimension Vista™ Total Iron Binding Capacity (TIBC) Calibrator is intended for use in the calibration of the TIBC method on the Dimension Vista™ system.

Prescription Use____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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