K070552

APR 30 2007

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 H Piestrak
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P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: February 26, 2007

Name of Product: Dimension Vista™ Ferritin Flex® reagent cartridge (FERR)
Dimension Vista™ LOCI 4 Calibrator

FDA Classification Name: Ferritin immunological test system (Class II)
Calibrator (Class II)

Predicate Device:

The following table describes the predicate devices, device classification, regulation and product code associated with this pre-market notification:

New Product	Predicate Device	510(k) number	Device Class	Regulation	Product Code
Ferritin (FERR) Flex® reagent cartridge for the Dimension Vista™ system (K6440)	Ferritin (FERR) Flex® reagent cartridge for the Dimension® clinical chemistry system (RF440)	K963498	II	866.5340	DBF
Dimension Vista™ LOCI 4 Calibrator	Dimension FERR Calibrator	K983548	II	862.1150	JIT

Device Description:

The Dimension Vista™ FERR Flex® reagent cartridge assay is a homogenous, sandwich chemiluminescent immunoassay based on LOCI™ technology. The LOCI™ reagents include two synthetic bead reagents and a biotinylated anti-ferritin monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains a photosensitizer dye. The second bead reagent (Chemibeads) is coated with a second anti-ferritin monoclonal antibody and contains chemiluminescent dye. Sample is incubated with biotinylated antibody and Chemibeads to form a particle/ferritin/biotinylated antibody sandwich. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the ferritin concentration in the sample.

The Dimension Vista™ LOCI 4 Calibrator is a five level, liquid calibrator. It is packaged as a kit of 10 vials, two vials each of five levels. The product matrix is 6% bovine serum albumin with buffer, stabilizer and preservatives. Level A is zero. Levels B through E contain Ferritin at the following target concentrations :

Level	Ferritin concentration
A	0 ng/mL
B	26 ng/mL
C	210 ng/mL
D	1050 ng/mL
E	2000 ng/mL

Values are assigned to new lots from a masterpool that is referenced to the WHO standard for FERR, 3 rd IS 94/572

Intended Use:

The FERR method is an *in-vitro* diagnostic test for the quantitative measurement of ferritin in human serum and plasma (lithium or sodium heparin and EDTA) on the Dimension Vista™ system. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

The LOCI 4 Calibrator is an *in vitro* diagnostic product for the calibration of the Ferritin (FERR) method on the Dimension Vista™ system.

Comparison to Predicate Device:

Both the Dimension Vista™ Ferritin Flex® reagent cartridge (FERR) assay (catalogue number K6440) and the predicate Dimension® Ferritin Flex® reagent cartridge assay (catalogue number RF440) employ prepackaged reagents for use on automated clinical chemistry test systems. A comparison of the important similarities and differences of these methods is provided in the following table:

Feature	**Dimension Vista™ Ferritin Flex® reagent cartridge (K6440)**	**Dimension Ferritin Flex® reagent cartridge (RF440)**
Intended Use	*in vitro* diagnostic use	*in vitro* diagnostic use
Sample Type	Serum and Plasma	Serum and Plasma
Assay Range	0- 2000 ng/mL	0- 1000 ng/mL
Technology	Sandwich format monoclonal antibody immunoassay	Sandwich format monoclonal antibody immunoassay
Detection	Chemiluminescent reaction measurement at 680 & 612 nm	Colorimetric rate measurement at 577 & 700 nm
Sample Size	2 µL	40 µL
Antibody source	Monoclonal mouse	Monoclonal mouse

Both the Dimension Vista™ LOCI 4 Calibrator and the predicate Dimension ® Ferritin Calibrator have the same intended use. A comparison of the important similarities and differences is provided in the following table:

Feature	Dimension Vista™ LOCI 4 Calibrator	Dimension® Ferritin Calibrator
Intended Use	Calibrate Ferritin on the Dimension Vista™ system	Calibrate Ferritin on the Dimension® clinical chemistry system
Analytes	Ferritin	Ferritin
Matrix	Bovine Serum Albumin	Bovine Serum Albumin
Traceable to:	WHO Standard for ferritin 3rd IS 94/572	WHO Standard for ferritin 3rd IS 94/572
Form	Liquid stored @ -10 to -20°C	Liquid stored @ 4 to 8°C
Volume	A 2.5 mL per vial B 1.5 mL per vial C 1.0 mL per vial D 1.0 mL per vial E 2.0 mL per vial	1 ml per vial
Levels	5 levels	5 levels

Comments on Substantial Equivalence:

Split sample comparison between the Dimension Vista™ Ferritin Flex® reagent cartridge assay and the Dimension® Ferritin Flex® reagent cartridge assay gave the following correlation statistics, when tested with clinical patient samples:

Method Comparison Data
Dimension Vista™ FERR vs. Predicate Method

Dimension Vista™	Predicate	Slope	Intercept	Correlation Coefficient (r)	n
FERR	Dimension ® Ferritin	1.01	1.48 ng/mL	0.996	158

Conclusion:

The Dimension Vista™ Ferritin Flex® reagent cartridge assay with the associated LOCI 4 Calibrator is substantially equivalent in principle and performance to the Dimension® Ferritin Flex® reagent cartridge assay based on the split sample comparison discussed above.

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
March 23, 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 30 2007

Dade Behring Inc.
c/o Ms. Lorraine H. Piestrak
Regulatory Affairs and Compliance Manager
P.O. Box 6101
Newark, DE 19714-6101

Re: k070552
Trade/Device Name: Dimension Vista™ Ferritin Flex® reagent cartridge
Dimension Vista™ LOCI 4 Calibrator
Regulation Number: 21 CFR 866.5340
Regulation Name: Ferritin Immunological Test System
Regulatory Class: Class II
Product Code: DBF, JIT
Dated: March 26, 2007
Received: March 27, 2007

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); 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) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070552

Device Name: Dimension Vista™ Ferritin Flex® reagent cartridge (FERR)

Indications For Use:

The FERR method is an *in vitro* diagnostic device for the quantitative measurement of ferritin in human serum and plasma (lithium or sodium heparin, and EDTA) on the Dimension Vista® System. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

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)

Marie M Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K070552

Indications for Use

510(k) Number (if known): K070552

Device Name: Dimension Vista™ LOCI 4 Calibrator

Indications For Use:

The Dimension Vista™ LOCI 4 Calibrator is an *in vitro* diagnostic device intended to be used to calibrate the ferritin (FERR) assay on the Dimension Vista™ system.

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

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Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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