K071224

510(k) Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Lorraine H Piestrak
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NOV 1 3 2007

Date of Preparation: April 30, 2007

Name of Product: 1. Dimension Vista® Vitamin B12 Flex® reagent cartridge (B12)
2. Dimension Vista® Folate Flex® reagent cartridge (FOL)
3. Dimension Vista® LOCI 4 Calibrator

FDA Classification Name: 1. Radioassay, Vitamin B12
2. Acid, Folic, Radioimmunoassay
3. Calibrator

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
B12 Flex® reagent cartridge for the Dimension Vista® system	VB12 for the ADVIA Centaur® System	K041133	II	862.1810	CDD
FOL Flex® reagent cartridge for the Dimension Vista® system	FOL for the ADVIA Centaur® system	K010050	II	862.1295	CGN
LOCI 4 Calibrator for the Dimension Vista® system	FERR Calibrator for the Dimension system	K983548	II	862.1150	JIX

Device Description:

B12

The Dimension Vista® Vitamin B12 method is a homogeneous, competitive chemiluminescent immunoassay based on LOCI™ technology. LOCI™ reagents include two synthetic bead reagents and biotinylated intrinsic factor (IF). The first bead reagent (Chemibeads) is coated with a B12 derivative and contains a chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains photosensitive dye. The patient sample is pretreated with NaOH to release the serum B12 from its carrier proteins. Potassium cyanide (KCN) is added to convert all the forms of B12 into a single, cyanocobalamin form, and dicyanocobinamide is added to keep the B12 from rebinding with the carrier proteins. After the sample pretreatment, the biotinylated IF and Chemibead reagents are added sequentially to the reaction vessel. Vitamin B12 from the sample competes with the B12-Chemibead for a limited amount of biotinylated IF. Sensibeads are then added and bind to the biotin to form bead pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from the Sensibeads which diffuses to the

Chemibeads triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is an inverse function of the concentration of vitamin B12 in the sample.

FOL

The Dimension Vista® Folate method is a homogenous, competitive chemiluminescent immunoassay based on LOCI™ technology. LOCI™ reagents include two synthetic bead reagents and labeled folate binding protein (FBP). The first bead reagent (Chemibeads) is coated with a folic acid derivative and contains a chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains photosensitive dye. Before the immunological portion of the reaction is initiated, the patient sample is pretreated with NaOH and DTT to release serum folate from endogenous folate binding protein and to maintain 5-methyl tetrahydrofolate in its reduced form. After the sample pretreatment, Chemibeads and labeled folate binding reagent are added sequentially to the reaction vessel. Folate from the patient sample competes with the folate-Chemibead for a limited amount of labeled FBP. Sensibeads are then added and bind to the biotinylated portion of the labeled FBP to form bead pair immunocomplexes. Illumination of the complex by light at 680 nm generates singlet oxygen from the Sensibeads which diffuses to the Chemibeads triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is an inverse function of the concentration of folate in the sample.

Calibrator

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, Vitamin B12, and Folate at the following target concentrations :

Level	Ferritin ng/mL	B12 pg/mL	Folate ng/mL
A	0	0	0.0
B	26	200	2.5
C	210	500	5.0
D	1050	1000	10.0
E	2000	2100	21.0

Values are assigned to new lots from a masterpool that is referenced to the WHO standard for FERR, 3 rd IS 94/572 and United States Pharmacopoeia materials for B12 and Folate

Intended Use:

B12

The B12 method is an *in-vitro* diagnostic test for the quantitative measurement of Vitamin B12 in human serum and plasma on the Dimension Vista® system.

FOL

The FOL method is an *in-vitro* diagnostic test for the quantitative measurement of folate in human serum and plasma on the Dimension Vista® system.

Calibrator

The LOCI 4 Calibrator is an *in vitro* diagnostic product for the calibration of the Ferritin (FERR), Vitamin B12 (B12), and Folate (FOL) methods on the Dimension Vista® system.

Comparison to Predicate Device:

Both the Dimension Vista® Vitamin B12 Flex® reagent cartridge (B12) assay and the predicate VB12 assay on the ADVIA Centaur® System 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® B12 Flex® reagent cartridge**	**VB12 on the ADVIA Centaur® System**
Intended Use	*in vitro* diagnostic use	*in vitro* diagnostic use
Sample Type	Serum and Plasma	Serum and Plasma
Assay Range	50 - 2000 pg/mL	45 - 2000 pg/mL
Technology	Competitive format homogeneous immunoassay	Competitive format heterogeneous immunoassay
Detection	Chemiluminescent reaction measurement at 680 & 612 nm	Chemiluminescent reaction Wavelength not disclosed
Sample Size	15 µL	100 µL
Binding Protein	Purified porcine Intrinsic Factor	Purified porcine Intrinsic Factor

Both the Dimension Vista® Folate Flex® reagent cartridge (FOL) assay and the predicate Folate(FOL) assay on the ADVIA Centaur® System 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® FOL Flex® reagent cartridge**	**FOL on the ADVIA Centaur® System**
Intended Use	*in vitro* diagnostic use	*in vitro* diagnostic use
Sample Type	Serum and Plasma	Serum and Red Blood Cells
Assay Range	0.5 - 20 ng/mL	0.35 - 24 ng/mL
Technology	Competitive format immunoassay	Competitive format immunoassay
Detection	Chemiluminescent reaction measurement at 680 & 612 nm	Chemiluminescent reaction Wavelength not disclosed
Sample Size	10 µL	150 µL
Binding protein	Folate Binding Protein (FBP) complexed with biotinylated mouse monoclonal anti-FBP antibody	Biotinylated Folate Binding Protein

Both the Dimension Vista® LOCI 4 Calibrator and the predicate Dimension® Ferritin Calibrator have similar 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, Vitamin B12 and Folate on the Dimension Vista® system	Calibrate Ferritin on the Dimension® clinical chemistry system
Analytes	Ferritin, Vitamin B12, Folate	Ferritin
Matrix	Bovine Serum Albumin	Bovine Serum Albumin
Traceable to:	WHO Standard for ferritin 3rd IS 94/572 and USP material for B12, and Folate	WHO Standard for ferritin 3rd IS 94/572
Form	Liquid stored @ -10 to -20°C	Liquid stored @ 2 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

Note: The Dimension Vista® LOCI 4 Calibrator with Ferritin only is currently under review by FDA in K070552.

Comments on Substantial Equivalence:

Split sample comparison between the Dimension Vista® B12 and FOL Flex® reagent cartridge assays and ADVIA Centaur® system VB12 and FOL assay gave the following correlation statistics, when tested with clinical patient samples:

Method Comparison Data
Dimension Vista® B12 and FOL vs. Predicate Method

Dimension Vista®	Predicate	Slope	Intercept	Correlation Coefficient (r)	n
B12	VB12 for the ADVIA Centaur® System	0.93	-14.4 pg/mL	0.98	124
FOL	FOL for the ADVIA Centaur® system	1.02	-0.07 ng/mL	0.96	110

Conclusion:

The Dimension Vista® Vitamin B12 and Folate Flex® reagent cartridge assays with the associated LOCI 4 Calibrator are substantially equivalent in principle and performance to the ADVIA Centaur VB12 and FOL assays based on the split sample comparison discussed above.

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
April 30, 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
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NOV 1 3 2007

Dade Behring, Inc.
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M/S 514
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Re: k071224

Trade Name: Dimension Vista Vitamin B12 Flex reagent cartridge (B12), Dimension Vista Folate Flex reagent cartridge (FOL) and Dimension Vista LOCI 4 Calibrator
Regulation Number: 21 CFR 862.1295
Regulation Name: Folic acid test system
Regulatory Class: Class II
Product Code: CDD, CGN and JIX

Dated: October 15, 2007
Received: October 22, 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 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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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

510(k) Number (if known): K071224

Device Name: Dimension Vista® Vitamin B12 Flex® reagent cartridge (B12)

Indications For Use:

The B12 Flex® reagent cartridge is an *in vitro* diagnostic test for the quantitative measurement of Vitamin B12 in human serum and plasma on the Dimension Vista® system. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

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

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

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Dev...
Evaluation and Safety

510(k) K071224

Indications for Use

510(k) Number (if known): K071224

Device Name: Dimension Vista® Folate Flex® reagent cartridge (FOL)

Indications For Use:

The FOL Flex® reagent cartridge is an *in vitro* diagnostic test for the quantitative measurement of folate in human serum and plasma on the Dimension Vista® system. Measurements obtained by this device are used in the diagnosis and treatment of megaloblastic anemia.

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

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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

10(k) K071224

Indications for Use

510(k) Number (if known): K071224

Device Name: Dimension Vista® LOCI 4 Calibrator

Indications For Use:

The LOCI 4 Calibrator is an *in vitro* diagnostic product for the calibration of Ferritin (FERR), Vitamin B12 (B12), and Folate (FOL) methods on the Dimension Vista® system.

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

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

Carol C. Benson

Division Sign-Off

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