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510(k) Summary
Dimension Vista VB12

NOV 3 0 2012

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

The assigned 510(k) number is: ____ **k121994**_____

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer:	Siemens Healthcare Diagnostics Inc. P.O. Box 6101 Newark, DE 19714
Contact Information:	Siemens Healthcare Diagnostics Inc. P.O. Box 6101 Newark, DE 19714 Attn: A. Kathleen Ennis Tel: 302-631-9352 FAX # 302-631-6299
Date of Preparation:	November 9, 2012

2. Device Name
Proprietary Name

- Dimension Vista® LOCI Vitamin B12 Flex reagent cartridge / Class II
- Dimension Vista® LOCI 4 CAL / Class II

Common Name

- Vitamin B12 Assay
- Calibrator

FDA Classification

- Radioassay Vitamin B12 - code CDD
- Calibrator Multianalyte - code JIX

3. Identification of the Predicate Device

- Roche Elecsys Vitamin B_{12} Test System - k060755
- Dimension Vista® LOCI 4 Calibrator – k071224

FDA Guidance Document(s):

- "Bundling Multiple Devices or Multiple Indications in a Single Submission"-11/26/2003

4. Device Description(s):

Method

The LOCI 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 (Chemibead) is coated with a B12 derivative and contains a chemiluminescent dye. The second bead reagent (Sensibead) is coated with streptavidin and contains photosensitive dye. The patient sample is pretreated with sodium hydroxide (NaOH) and dithioerythritol (DTE) 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. Sensibead reagent is then added and binds 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.

Calibrator

LOCI 4 CAL is a multi-analyte liquid, frozen, product containing Ferritin from human liver, Folate, and Vitamin B12. CAL A is a HEPES buffer solution whereas CAL B – E are prepared in a bovine serum albumin base.
The kit consists of ten vials, two each of five levels containing 2 mL per vial. Description of the manufacturing, value assignment and stability testing processes are provided.

5. Device Intended Use:

Method

The VB12 method is an *in vitro* diagnostic test for the quantitative measurement of vitamin B12 in human serum and plasma on the Dimension Vista® System. Measurements of vitamin B12 are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

Calibrator

The LOCI 4 CAL is an *in vitro* diagnostic product for the calibration of the LOCI Ferritin (FERR), LOCI Folate (FOL) and LOCI Vitamin B12 (VB12) methods on the Dimension Vista® System.

6. Medical device to which equivalence is claimed:

Substantial Equivalence:
The Dimension Vista® LOCI Vitamin B12 Flex® reagent cartridge is substantially equivalent to the Roche Elecsys Vitamin B12 Test System (K060755) . The Dimension Vista® LOCI 4 Calibrator (KC640A) is substantially equivalent to the Dimension Vista® LOCI 4 Calibrator, cat.# KC640 (K071224).

Comparison to Predicate Device:

The proposed Siemens Healthcare Diagnostics Dimension Vista® VB12 method and the predicate Roche Elecsys® Vitamin B12 Test System(K060755) are both *in vitro* diagnostic immunoassays intended for the quantitative measurement of vitamin B12 in serum and plasma.

The Siemens Healthcare Diagnostics Dimension Vista® LOCI 4 Calibrator, cat. # KC640A, and the predicate Dimension Vista® LOCI 4 Calibrator, cat. # KC640 (K071224) are both used for the calibration of the LOCI Ferritin (FERR), LOCI Folate (FOL) and LOCI Vitamin B12 (VB12) methods on the Dimension Vista® System.
A comparison summary of the features of the products is included in the following table.

Method:

Item	Device **Dimension Vista® VB12 Flex® reagent cartridge**	Predicate **Roche Elecsys Vitamin B12 Test System(K060755)**
Similarities		
Intended Use	*in vitro* diagnostic test for the quantitative measurement of vitamin B12 in human serum and plasma	Binding assay for the in vitro quantitative determination of vitamin B12 in human serum and plasma
Sample Types	Serum and Plasma	Serum and Plasma
Measurement method	Chemiluminescent: Homogenous sandwich immunoassay based on LOCI® technology	Chemiluminescent: Electrochemiluminescence Immunoassay "ECLIA"
Differences		
Instrument	The Dimension Vista® Vitamin B12 method (VB12) is for use on the Dimension Vista® System.	The Roche Vitamin B12 Assay is for use on Elecsys and **cobas e** immunoassay analyzers.
Measuring Range	60 – 2000 pg/mL	30 – 2000 pg/mL
Lower limit of the assay	60 pg/mL (Functional Sensitivity)	30 pg/mL (Analytical Sensitivity)
Sample Size	12 uL	15 uL

Calibrator:

Item	Device Modified LOCI 4 CAL	Predicate LOCI 4 CAL (k071224)
Similarities		
Intended Use	The LOCI 4 CAL is an *in vitro* diagnostic product for the calibration of the LOCI Ferritin (FERR), LOCI Folate (FOL) and LOCI Vitamin B12 (VB12) methods on the Dimension Vista® System.	The LOCI 4 CAL is an *in vitro* diagnostic product for the calibration of the LOCI Ferritin (FERR), LOCI Folate (FOL) and LOCI Vitamin B12 (B12) methods on the Dimension Vista® System.
Traceability		
Ferritin	Traceable to the World Health Organization (WHO) *WHO Standard for Ferritin, 3rd IS 94/572*	Traceable to the World Health Organization (WHO) *WHO Standard for Ferritin, 3rd IS 94/572*
Folate	United States Pharmacopeia Grade Folic Acid	United States Pharmacopeia Grade Folic Acid
Vitamin B12	United States Pharmacopeia Grade vitamin B12	United States Pharmacopeia Grade vitamin B12
Form	Frozen Liquid	Frozen Liquid
Differences		
Matrix	HEPES Buffer Level A	BSA-based matrix Level A
	2% BSA in Level B - E	6% BSA in Level A - E
Target Concentrations VB12	Level A : 45 pg/mL Level B 200 pg/mL Level C 500 pg/mL Level D 1000 pg/mL Level E: 2200 pg/mL	Level A : 0 pg/mL Level B 200 pg/mL Level C 500 pg/mL Level D 1000 pg/mL Level E: 2100 pg/mL
Folate	Level A: 0 ng/mL Level B: 2.5 ng/mL Level C: 5.0 ng/mL Level D: 10.0 ng/mL Level E: 21.0 ng/mL	Level A: 0 ng/mL Level B: 2.5 ng/mL Level C: 5.0 ng/mL Level D: 10.0 ng/mL Level E: 21.0 ng/mL
Ferritin	Level A: 0 ng/mL Level B: 25 ng/mL Level C: 210 ng/mL Level D: 1050 ng/mL Level E: 2200 ng/mL	Level A: 0 ng/mL Level B: 25 ng/mL Level C: 210 ng/mL Level D: 1050 ng/mL Level E: 2200 ng/mL

Comments on Substantial Equivalence:

Method

The Siemens Healthcare Diagnostics Dimension Vista® VB12 method and the predicate Roche Elecsys Vitamin B12 Assay are both *in vitro* diagnostic immunoassays intended for the measurement of vitamin B12 in serum and plasma.

Reproducibility testing was conducted for the Dimension Vista® VB12 method in accordance with the CLSI/NCCLS Approved Guideline for User Evaluation of Precision Performance of Clinical Chemistry Devices EP5-A2. For each test level, a single test from two independent cups was analyzed twice per day for 20 days. The repeatability and within-lab standard deviations were calculated by the analysis of variance method.

Typical precision observed for the Dimension Vista® VB12 method is summarized below:

Material	Mean pg/mL	Repeatability		Within-Lab Precision	
		SD	%CV	SD	%CV
QC L1*	275	11.0	4.0	19.2	7.0
QC L2*	518	8.2	1.6	20.3	3.9
QC L3*	682	16.3	2.4	20.1	3.0
Serum Pool 1	238	8.4	3.5	18.0	7.6
Li Heparin Plasma Pool	365	8.9	2.4	12.3	3.4
Serum Pool 2	1007	14.4	1.4	21.0	2.1
Serum Pool 3	1716	20.6	1.2	32.7	1.9

*BioRad Liquichek™ Immunoassay Plus Controls, BioRad Laboratories, Irvine, CA

Seventy-one matched serum, lithium heparin plasma, sodium heparin and EDTA plasma samples were analyzed on the Dimension Vista® system. Each plasma type was analyzed versus serum. The least squares regression statistics are as follows:

Sample Type (vs Serum) n = 71	Slope	Intercept pg/mL	Correlation Coefficient (r)
Lithium Heparin Plasma	0.993	-3.2	0.999
Sodium Heparin Plasma	0.995	-3.3	0.999
EDTA Plasma	0.999	-14.4	0.998

A method comparison between the Dimension Vista® VB12 assay and the Vitamin B12 assay on the Roche Elecsys® System was performed with one hundred sixty-two (162) native serum samples across the proposed assay range. The samples ranged from 69 to 1829 pg/mL on the Roche Elecsys, and 60 to 1963 pg/mL on the Dimension Vista® and included thirty-two (32) samples with known Intrinsic Factor Binding Antibody (IFBA) titers ranging from 7 to 133.85 U/mL.

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Passing-Bablok regression analysis of the results yielded the following:

Passing - Bablok Regression			
	Bias	95% CI	
Constant	-7.64	-17.89	to -0.48
Proportional	0.985	0.965	to 1.004

The correlation coefficient, using least squares regression, for this data set (R) is 0.993

Conclusion:
The Siemens Healthcare Diagnostics Dimension Vista® VB12 method and the predicate Roche Elecsys Vitamin B12 Assay method (K060755) are substantially equivalent based on their intended use and performance characteristics as described above. The calibrator products, the Siemens Healthcare Diagnostics modified Dimension Vista® LOCI 4 calibrator and the predicate Dimension Vista® LOCI 4 (K071224) are also substantially equivalent in its design and intended use with their respective assay systems.

A. Kathleen Ennis
Regulatory Affairs Manager
September 26, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD. 20993-002

November 30, 2012

Siemens Healthcare Diagnostics, Inc.
c/o A. Kathleen B. Ennis
500 GBC Drive
Newark, DE 19714

Re: k121994
Trade/Device Name: Dimension Vista® LOCI Vitamin B12 Flex reagent cartridge and Dimension Vista® LOCI 4 CAL
Regulation Number: 21 CFR 862.1810
Regulation Name: Vitamin B12 Test System
Regulatory Class: Class II
Product Code: CDD, JIX
Dated: October 18, 2012
Received: October 19, 2012

Dear Ms. Ennis:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121994

Device Name: Dimension Vista® LOCI Vitamin B12 Flex reagent cartridge
Dimension Vista® LOCI 4 CAL

Indications for Use: The VB12 method is an *in vitro* diagnostic test for the quantitative measurement of vitamin B12 in human serum and plasma on the Dimension Vista® System. Measurements of vitamin B12 are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

The LOCI 4 CAL is an *in vitro* diagnostic product for the calibration of LOCI Ferritin (FERR), LOCI Folate (FOL), and LOCI Vitamin B12 (VB12) methods on the Dimension Vista® System.

Prescription Use __x_____ AND/OR Over-The-Counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yeung Chan
Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)

510(k) K121994