

**510(k) Summary of Safety and Effectiveness for the
Dimension Vista® LOCI CA 125 (CA125) Flex® Reagent Cartridge**

Dimension Vista® LOCI® 6 Calibrator

APR 12 2011

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.

A. 510(k) Number: k100321

B. Date of Preparation: February 2, 2010

C. Proprietary and Established Names:

LOCI CA 125 Flex® Reagent Cartridge

Dimension Vista® LOCI 6 Calibrator

D. Applicant:

Siemens Healthcare Diagnostics Inc.

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

Pamela A. Jurga, Regulatory & Clinical Affairs Specialist

Office Number: (302) 631-8891 fax Number: (302) 631-6299

E. Regulatory Information:

LOCI CA125 Flex® Reagent Cartridge:

1. Regulation section: 21 CFR § 866.6010 Tumor-Associated antigen immunological test system
2. Classification: Class II
3. Product Code: LTK – Test, Epithelial Ovarian Tumor-Associated Antigen (Ca125)
4. Panel: Immunology

LOCI 6 Calibrator:

1. Regulation section: 21 CFR § 862.1150 Calibrator
2. Classification: Class II
3. Product Code: JIX – Calibrator, Multi-Analyte Mixture
4. Panel: Immunology

F. Predicate Device:

The predicate device used to demonstrate substantial equivalence to the LOCI CA125II™ Flex® Reagent Cartridge is the CA 125II Assay for the ADVIA Centaur System previously cleared under k020828.

The predicate device used to demonstrate substantial equivalence to the Dimension Vista® LOCI 6 Calibrator is the Dimension Vista® LOCI 5 Calibrator previously cleared under k071597 and k071603.

G. Device Description:

The LOCI CA 125II™ method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI® technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated anti-CA 125 monoclonal antibody (M11) fragment. The first bead reagent (Chemibeads) is coated with an anti-CA125 monoclonal antibody (OC 125) and contains a chemiluminescent dye. The use of the M11 antibody in combination with OC 125 defines this method as a second generation CA 125 assay. The second bead reagent (Sensibeads) is coated with streptavidin and contains a photosensitizer dye. Sample is incubated with biotinylated antibody and Chemibeads to form bead-CA 125-biotinylated antibody sandwiches. 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 CA 125 concentration in the sample.

The LOCI 6 calibrator is a multi-analyte liquid, frozen bovine serum albumin based product containing Alpha-Fetoprotein from human cord blood, Carcinoembryonic Antigen from human cell culture and CA 125 from human cell culture. The kit consists of ten vials, two vials per level (A-E), 2.0 mL per vial. Description of the manufacturing, value assignment and stability testing process are provided in this submission report.

H. Intended Use:

The LOCI CA 125 II™ method is an *in vitro* diagnostic test for the quantitative measurement of CA 125 antigen in human serum and lithium heparin and EDTA plasma on the Dimension Vista® System. Measurements of CA 125 are used as an aid in monitoring disease progress or response to therapy or for the recurrent or residual disease for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay values should be used in conjunction with other clinical methods used for monitoring ovarian cancer. It is recommended that the LOCI CA 125 II method be used in conjunction with signs and symptoms of a clinical evaluation by a physician trained and experienced in the management of gynecological cancers. This assay is not intended for screening or diagnosis of ovarian cancer or for use on any other system.

The LOCI 6 CAL is an *in vitro* diagnostic product for the calibration of Alpha-Fetoprotein (AFP), Carcinoembryonic Antigen (CEA) and Cancer Antigen125II™ (CA125) methods on the Dimension Vista® system.

I. Substantial Equivalence Information:

The LOCI CA 125II™ method is substantially equivalent to other CA125 test systems such as the ADVIA Centaur CA125II assay (k020828). The LOCI 6 calibrator is substantially equivalent to other calibrators such as the LOCI 5 calibrator (k071597 and k071603). The following table provides a comparison of the important similarities and differences:

Feature	LOCI CA 125II™ Flex® Reagent cartridge	CA 125II Assay for the ADVIA Centaur System (K020828)
Intended Use	The LOCI CA 125 II™ method is an <i>in vitro</i> diagnostic test for the quantitative measurement of CA 125 antigen in human serum and lithium heparin and EDTA plasma on the Dimension Vista® System. Measurements of CA 125 are used as an aid in monitoring disease progress or response to therapy or for the recurrent or residual disease for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay values should be used in conjunction with other clinical methods used for monitoring ovarian	For <i>in vitro</i> diagnostic use in the quantitative, serial determination in human serum and to aid in the management of patients with ovarian carcinoma using the ADVIA Centaur and ADVIA Centaur XP systems. The test is intended for use as an aid in monitoring patients who are clinically free of disease and should be used in conjunction with other clinical methods used for monitoring ovarian cancer. Serial testing for CA 125 in the serum of patients who are clinically free of disease should be used in conjunction with other clinical methods used for early detection of cancer recurrence. The test is also intended for

	cancer. It is recommended that the LOCI CA 125 II method be used in conjunction with signs and symptoms of a clinical evaluation by a physician trained and experienced in the management of gynecological cancers. This assay is not intended for screening or diagnosis of ovarian cancer or for use on any other system.	use as an aid in the management of ovarian cancer patients with metastatic disease by monitoring the progression or regression of disease in response to treatment. It is recommended that the ADVIA Centaur CA 125 II assay be used under the order of a physician trained and experienced in the management of gynecological cancers. This assay is not intended for screening or diagnosis of ovarian cancer or for use on any other system.
Sample Type	Serum and lithium heparin and EDTA plasma	Serum
Measuring Range	1.5 -1000 U/mL	2-600 U/mL
Sample Size	5 µL	50 µL
Measurement	Chemiluminescent: Homogenous sandwich immunoassay based on LOCI® technology	Chemiluminescent: Two site sandwich immunoassay using direct chemiluminometric technology

Feature	LOCI 6 calibrator	LOCI 5 Calibrator k071597 and k071603
Intended Use	The LOCI 6 CAL is an <i>in vitro</i> diagnostic product for the calibration of Alpha-Fetoprotein (AFP), Carcinoembryonic Antigen (CEA) and Cancer Antigen125II™ (CA125) methods on the Dimension Vista® system.	an <i>in vitro</i> diagnostic product for the calibration of Alpha-Fetoprotein (AFP), Carcinoembryonic Antigen (CEA) methods on the Dimension Vista® system.
Matrix	BSA-based matrix	BSA-based matrix
Preparation	Liquid: Provided ready to use.	Liquid: Provided ready to use.
Target Concentrations CA 125	Level 1 (CAL A): 0 U/mL Level 2 (CAL B): 8 U/mL Level 3 (CAL C): 60 U/mL Level 4 (CAL D): 250 U/mL Level 5 (CAL E): 1050 U/mL	None
Storage	Store at -15 to - 25 °C.	Store at 2 to 10°C.

J. Conclusion:

The LOCI CA 125II™ method Flex® reagent cartridge is substantially equivalent to the ADVIA Centaur CA125II assay (k020828). Comparative testing described in the submission report demonstrates substantial equivalent performance.

The Dimension Vista® LOCI 6 CAL is substantially equivalent to the Dimension Vista® LOCI 5 CAL (k071597 and k071603).



Food and Drug Administration
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Siemens Healthcare Diagnostics
c/o Ms. Pamela A. Jurga
Regulatory and Clinical Affairs Specialist
PO Box 6101
Mailstop 514
Newark, DE 19714-6101

APR 12 2011

Re: k100321

Trade/Device Name: Dimension Vista® LOCI CA125 Flex® reagent cartridge
Dimension Vista® LOCI 6 Calibrator

Regulation Number: 21 CFR §866.6010

Regulation Name: Tumor-Associated antigen immunological test system

Regulatory Class: Class II

Product Code: LTK, JIT

Dated: March 31, 2011

Received: April 1, 2011

Dear Ms. Jurga:

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 class II (Special Controls), 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.

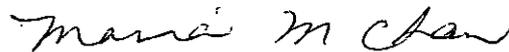
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety 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,



Maria M. Chan, 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):

k100321

Device Name:

Dimension Vista® CA 125 Flex® Reagent

Indications For Use:

The LOCI CA 125 II™ method is an *in vitro* diagnostic test for the quantitative measurement of CA 125 antigen in human serum and lithium heparin and EDTA plasma on the Dimension Vista® System. Measurements of CA 125 are used as an aid in monitoring disease progress or response to therapy or for the recurrent or residual disease for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay values should be used in conjunction with other clinical methods used for monitoring ovarian cancer. It is recommended that the LOCI CA 125 II method be used in conjunction with signs and symptoms of a clinical evaluation by a physician trained and experienced in the management of gynecological cancers. This assay is not intended for screening or diagnosis of ovarian cancer or for use on any other system.

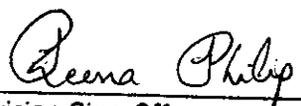
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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



Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K k100321

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Indications For Use Statement

510(k) Number (if known): k100321

Device Name:

Dimension Vista® LOCI 6 Calibrator

Indications for Use:

The LOCI 6 CAL is an in vitro diagnostic product for the calibration of Alpha-Fetoprotein (AFP), Carcinoembryonic Antigen (CEA), and CA 125 (CA125) methods on the Dimension Vista® System.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use _____
(21 CFR 801 Subpart C)

(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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