510(k) Summary for Dimension Vista® CEA Flex® reagent cartridge Dimension® Vista LOCI 5 Calibrator

JUN 25 2008

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.

The assigned 510(k) number is: K071603

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

Manufacturer:
Siemens Healthcare Diagnostics
P.O. Box 6101
Newark, Delaware 19714

Contact Information:
Siemens Healthcare Diagnostics
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: June 2, 2008

2. Device Name: Dimension Vista® CEA Flex® reagent cartridge
Dimension Vista® LOCI 5 Calibrator
Classification: Class II; Class II
Product Code: DHX; JIX
Panel: Immunology (82) and Clinical Chemistry (75)

3. Identification of the Legally Marketed Devices:

Beckman Access® CEA Reagents on the Access® Immunoassay System - K031270

4. Device Descriptions:

Dimension Vista® CEA Flex® reagent cartridge
The CEA method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI™ technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated anti-CEA monoclonal antibody fragment. The first bead reagent (Chemibeads) is coated with an anti-CEA monoclonal antibody and contains chemiluminescent dye. 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-CEA-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 CEA concentration in the sample.

Dimension Vista® LOCI 5 Calibrator
LOCI 5 CAL is a liquid, multi-analyte, bovine serum albumin based product containing CEA from human tissue culture.

5. **Device Intended Uses:**

Dimension Vista® CEA Flex® reagent cartridge:
The CEA method is an in vitro diagnostic test for the quantitative measurement of carcinoembryonic antigen in human serum and sodium or lithium heparinized plasma on the Dimension Vista® System. Measurements of carcinoembryonic antigen are used as an aid in the management of cancer patients in whom changing CEA concentrations have been observed.

Dimension Vista® LOCI 5 Calibrator:
For the calibration of the Carcinoembryonic Antigen (CEA) method on the Dimension Vista® System.

6. **Medical device to which equivalence is claimed and comparison information:**

The Dimension Vista® CEA Flex® reagent cartridge and Dimension Vista® LOCI 5 Calibrator are substantially equivalent to the Beckman Access® CEA Reagents on the Access® Immunoassay System (K031270). The Dimension Vista® CEA assay, like Beckman Access® CEA method is an *in vitro* diagnostic test for the quantitative measurement of CEA in human serum.

Similarities		
Item	Device	Predicate
Intended Use	The CEA method is an *in vitro* diagnostic test for the quantitative measurement of carcinoembryonic antigen in human serum and sodium or lithium heparinized plasma on the Dimension Vista® System. Measurements of carcinoembryonic antigen are used as an aid in the management of cancer patients in whom changing CEA concentrations have been observed.	The Access CEA assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Carcinoembryonic Antigen (CEA) levels in human serum, using the Access Immunoassay System. CEA measured by the Access Immunoassay System is used as an aid in the management of cancer patients.
Measuring Range	0.2– 1000.0 ng/mL	0.1– 1000.0 ng/mL
Measurement method	Chemiluminescent: homogenous, sandwich chemiluminescent immunoassay based on LOCI® technology.	Chemiluminescent: paramagnetic particle, chemiluminescent immunoassay

Differences		
Item	Device	Predicate
Principles of Procedure	The CEA method is a homogenous, sandwich chemiluminescent immunoassay based on LOCI® technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated anti-CEA monoclonal antibody fragment. The first bead reagent (Chemibeads) is coated with an anti-CEA monoclonal antibody and contains chemiluminescent dye. 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-CEA-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 Access CEA assay is a two-site immunoenzymatic "sandwich" assay using two mouse monoclonal anti-CEA antibodies (MAb) which react with different epitopes of CEA. A sample is added to a reaction vessel, along with the first anti-CEA MAb-alkaline phosphatase conjugate and the second anti-CEA MAb bound to paramagnetic particles. The incubation is followed by a magnetic separation and washing. A chemiluminescent substrate, Lumi-Phos* 530, is added to the reaction vessel and light generated by the reaction is measured with a luminometer. The light production is proportional to the concentration of CEA in the sample. The amount of analyte in the sample is determined by means of a stored, multi-point calibrator curve.
Sample Types	Serum and Plasma	Serum
Sample Size	2 uL	10 uL
Precision	Repeatability: 1.3 - 2.9 %CV Within Lab: 2.1 – 3.6 %CV	Within Run: 3.01 – 3.97 %CV Total: 3.80 – 4.51 %CV

7. Device Performance Characteristics:

Method Comparison

Regression Statistics[a]

Comparative Method	Slope	Intercept ng/mL [µg/L]	Correlation Coefficient	n
ACCESS® CEA	1.01	9.01	0.989	141[b]
ACCESS® CEA	1.04	0.44	0.970	46[c]

ACCESS® Immunoassay System is a registered trademark of Beckman Coulter, Inc.

a. CLSI/NCCLS EP9-A2 was used. The method used to fit the linear regression line was ordinary least squares.

b. The range of 141 values in the correlation study was 0.8 – 974 ng/mL [µg/L].

c. The range of 46 values in the correlation study was 0.8 –17.1 ng/mL [µg/L].

Precision

Material	Mean ng/mL [µg/L]	Standard Deviation (%CV) Repeatability	Within-Lab
Liquichek™ Immunoassay Plus Control			
Level 1	2.1	0.1 (2.9)	0.1 (3.4)
Level 2	26.2	0.6 (2.2)	0.8 (2.9)
Serum pool 1	0.9	0.02 (2.3)	0.02 (2.6)
Serum pool 2	12.8	0.3 (2.6)	0.4 (3.1)
Serum pool 3	67.5	1.3 (1.9)	1.6 (2.4)
Serum pool 4	478.0	6.2 (1.3)	10.1 (2.1)
Serum pool 5	756.4	13.6 (1.8)	24.9 (3.3)
Plasma pool	239.7	5.2 (2.2)	8.6 (3.6)

CLSI/NCCLS EP5-A2 was used. During each day of testing, two separate runs, with two test samples, for each test material, were analyzed for 20 days.

8. Conclusion:

These studies demonstrate correlation and equivalent precision performance between the Beckman Access® CEA Reagents on the Access® Immunoassay System and the Dimension Vista® CEA assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 2008

Dade Behring, Inc.
c/o Ms. Kathleen Dray-Lyons
Manager, Regulatory Affairs and Compliance
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101

Re: k071603
Trade/Device Name: Dimension Vista® CEA Flex® reagent cartridge
Dimension Vista® LOCI 5 Calibrator
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: DHX, JIX
Dated: June 2, 2008
Received: June 3, 2008

Dear Ms. Dray-Lyons:

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 advice for your device on our labeling regulation (21 CFR Part 801), 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Maria M. Chan

Maria M. Chan, Ph.D.
Acting Division 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 Statement

510(k) Number (if known): K071603

Device Name:

Dimension Vista® CEA Flex® reagent cartridge

Indications for Use:

The CEA method is an in vitro diagnostic test for the quantitative measurement of carcinoembryonic antigen in human serum and sodium or lithium heparin plasma on the Dimension Vista® System. Measurements of carcinoembryonic antigen are used as an aid in the management of cancer patients in whom changing CEA concentrations have been observed.

Prescription Use ____X___ **AND/OR** **Over-the-counter Use _____**
(Per 21 CFR 801 Subpart D) **(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)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K071603

Indications For Use Statement

Device Name: K071603

Dimension Vista® LOCI 5 Calibrator

Indications for Use:

For the calibration of the Carcinoembryonic Antigen (CEA) method on the Dimension Vista® System.

Prescription Use ___X___ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(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)

Maria M Chan

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K071603