

APR 27 2009

**510(k) Summary for  
Dimension Vista® AFP Flex® reagent cartridge**

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: K090236

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

Manufacturer: Siemens Healthcare Diagnostics Inc.  
500 GBC Drive, M/S 514  
P.O. Box 6101  
Newark, Delaware 19714-6101

Contact Information: Siemens Healthcare Diagnostics Inc.  
500 GBC Drive, M/S 514  
P.O. Box 6101  
Attn: Janet M. Fose  
Tel: 302-631-8826  
Fax: 302-631-6299

Preparation date: January 30, 2009

**B. Name of Device:**

Dimension Vista® AFP Flex® reagent cartridge

**C. Regulatory Information:**

CFR Section: 866.6010 – Tumor-Associated Antigen Immunological Test System  
Classification: Class II  
Classification Panel: Immunology (82)  
Product Code: LOJ

**D. Predicate Device:**

Dimension Vista® AFP Flex® reagent cartridge (K071597)

**E. Device Description:**

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

**F. Device Intended Use:**

The AFP method is an *in vitro* diagnostic test for the quantitative measurement of alpha-fetoprotein in human serum and lithium heparin plasma on the Dimension Vista® System. Measurements of alpha-fetoprotein are used as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.

**G. Substantial equivalence information:**

The Siemens Dimension Vista® AFP method modification to add lithium heparinized plasma as a sample type and the predicate Dimension Vista® AFP method are both *in vitro* diagnostic immunoassays intended for the measurement of alpha-fetoprotein (AFP) as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.

A comparison summary of the features of the products is included in the following table:

Similarities		
Feature	Device	Predicate
Intended Use	The AFP method is an <i>in vitro</i> diagnostic test for the quantitative measurement of alpha-fetoprotein in human serum and lithium heparin plasma on the Dimension Vista® System. Measurements of alpha-fetoprotein are used as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.	The AFP method is an <i>in vitro</i> diagnostic test for the quantitative measurement of alpha-fetoprotein in human serum on the Dimension Vista® System. Measurements of alpha-fetoprotein are used as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.
Standardization	Traceable to the World Health Organization (WHO) Reference preparation for human AFP (72/225)	Traceable to the World Health Organization (WHO) Reference preparation for human AFP (72/225)
Measurement method	Chemiluminescent: Homogenous sandwich immunoassay based on LOCI® technology	Chemiluminescent: Homogenous sandwich immunoassay based on LOCI® technology
Measuring Range	0.5– 1000.0 ng/mL	0.5– 1000.0 ng/mL
Sample	2 uL	2 uL

Differences		
Feature	Device	Predicate
Intended Use	The AFP method is an in vitro diagnostic test for the quantitative measurement of alpha-fetoprotein in human serum and lithium heparin plasma on the Dimension Vista® System. Measurements of alpha-fetoprotein are used as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures	The AFP method is an in vitro diagnostic test for the quantitative measurement of alpha-fetoprotein in human serum on the Dimension Vista® System. Measurements of alpha-fetoprotein are used as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures
Sample Types	Serum and plasma (lithium heparin)	Serum

**H. Comments about Substantial Equivalence:**

The same scientific technology and manufacturing processes are used for both devices. No formulation or design changes were made for the method modification. Comparative data for equivalency studies on human serum versus lithium heparinized plasma samples demonstrates good analytical and clinical agreement between the sample types. Summary results for the matched pairs study are described below:

Comparative Method	Slope	Intercept ng/mL	Correlation Coefficient	n
Dimension Vista® AFP	0.99	-0.05	0.997	70

**I. Conclusion:**

The Siemens Dimension Vista® AFP method modification to add lithium heparinized plasma as a sample type and the predicate Dimension Vista® AFP method (K071597) are substantially equivalent based on their intended use, device features and performance characteristics as described above.



Food and Drug Administration  
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Rockville MD 20850

Siemens Healthcare Diagnostics Inc.  
c/o Ms Janet M. Fose  
Regulatory Affairs Specialist  
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P.O. Box 6101  
Newark, DE 19714-6101

APR 27 2009

Re: k090236

Trade/Device Name: Dimension Vista® AFP Flex® reagent cartridge  
Regulation Number: 21 CFR 866.6010  
Regulation Name: Tumor-associated antigen immunological test system  
Regulatory Class: II  
Product Code: LOJ  
Dated: January 30, 2009  
Received: February 2, 2009

Dear Ms. Fose:

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.

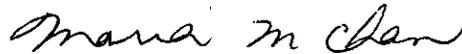
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); 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 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. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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, 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): K090236

Device Name: Dimension Vista® AFP Flex® reagent cartridge

Indication for Use:

The AFP method is an in vitro diagnostic test for the quantitative measurement of alpha-fetoprotein in human serum and lithium heparinized plasma on the Dimension Vista® System. Measurements of alpha-fetoprotein are used as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.

Prescription Use X  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use       
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

maria m chen

Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K090236