MAY 23 2008

510(k) Summary of Safety and Effectiveness
Dimension® TSHL Flex® reagent cartridge and
TSH Sample Diluent

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: K081074

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: Yuk-Ting Lewis Tel: 302-631-7626
Date of Preparation:	May 5, 2008

2. Device Name / Classification

Dimension® TSHL Flex® reagent cartridge / Class II
TSH Sample Diluent / Class II

3. Identification of the Predicate Device

Dimension Vista™ TSH Flex® reagent cartridge, K060090

4. Device Description

The Dimension® TSHL Flex® reagent cartridge is an in vitro diagnostic device that consists of prepackaged reagents in a plastic eight-well cartridge for use on the Dimension® EXL™ with LM system.

The TSH Sample Diluent is a liquid, bovine serum albumin based product with preservatives.

5. Device Intended Use

The TSHL method is an in vitro diagnostic test intended for the quantitative measurement of Thyroid Stimulating Hormone (TSH, thyrotropin) in human serum and plasma on the Dimension® EXL™ with LM system. Measurements of TSH are used in the diagnosis and monitoring of thyroid disease.

The TSH Sample Diluent is an in vitro diagnostic product for manual dilution of samples with elevated TSH results processed on the Dimension Vista® and Dimension® EXL™ with LM Systems.

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

The Dimension® TSHL Flex® reagent cartridge is substantially equivalent in intended use and technological characteristics to the Dimension® Vista TSH Flex® reagent cartridge. A comparison of features is provided.

Feature	**Predicate Device:** **Dimension Vista® TSH Flex® reagent cartridge**	**New Device:** **Dimension® TSHL Flex® reagent cartridge**
Intended Use	Both devices are for in vitro diagnostic use for the quantitative measurement of Thyroid Stimulating Hormone in human serum and plasma.	
Sample Type	Acceptable sample types are human serum and plasma.	
Assay Range	The Dimension Vista® TSH method has an assay range of 0.005-100 µIU/mL.	The Dimension® TSHL method has an assay range of 0.007-100 µIU/mL.
Technology	Both devices use LOCI® technology.	
Sample Size	Both devices use a sample volume of 12 µL.	
Reagents and antibody	Both devices use the same liquid reagents and antibody.	
Diluent	Both devices use the TSH Sample Diluent to manually dilute high samples.	
Instrument	The Dimension Vista® TSH Flex® is run on the Dimension Vista® analyzer.	The Dimension® TSHL Flex® is run on the Dimension® EXL™ with LM system.

Comparison Information

Method comparison studies were conducted on the Dimension® TSHL Flex® vs. the Dimension® Vista TSH Flex® reagent cartridge using two hundred-and-ten (210) serum samples. The data was analyzed using least squares linear regression. The Dimension® TSHL Flex® demonstrated excellent correlation to the predicate device as evidenced by a correlation coefficient = 0.997. The resulting regression statistics are shown below.

Slope	1.05
95% CI	1.0442 to 1.0649
y-int	-0.04 µIU/mL
r	0.997
Sy,x	1.708 µIU/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 31 2008

Siemens Healthcare Diagnostics, Inc.
c/o Yuk-Ting Lewis
P.O. Box 6101, M/S 514
Newark, DE 19714

Re: k081074
Trade/Device Name: Dimension TSHL Flex reagent cartridge
and TSH sample diluents with models rf 612 and kd691
Regulation Number: 21 CFR §862.1690
Regulation Name: Thyroid Stimulating Hormone test system.
Regulatory Class: Class II
Product Code: JLW
Dated: May 13, 2008
Received: May 14, 2008

Dear Ms. Lewis:

This letter corrects our substantially equivalent letter of May 23, 2008.

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); 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 100-1050.

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

Indication for Use

510(k) Number (if known): k081074

Device Name: Dimension® TSHL Flex® reagent cartridge
TSH Sample Diluent

Indications For Use:

Method
The TSHL method is an *in vitro* diagnostic test for the quantitative measurement of Thyroid Stimulating Hormone (TSH, thyrotropin) in human serum and plasma on the Dimension® EXL™ with LM System. Measurements of TSH are used in the diagnosis and monitoring of thyroid disease.

Diluent
The TSH Sample Diluent is an in vitro diagnostic product for manual dilution of samples with elevated TSH results processed on the Dimension Vista® and Dimension® EXL™ with LM systems.

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)

Carol C Benson

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

510(k) k081074