JUL - 3 2008

510(k) Summary of Safety and Effectiveness
Dimension® TNI Flex® reagent cartridge and
CTNI 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: K081643

1. Submitter's Contact Information and Date of Preparation

Submitter's Contact Information:

Mrs. Yuk-Ting Lewis
Siemens Healthcare Diagnostics Inc.
P.O. Box 6101
Newark, DE 19714
Tel: 302-631-7626

Date of Preparation: June 3, 2008

2. Proprietary Device Name / FDA Classification Name

Dimension® TNI Flex® reagent cartridge	Immunoassay Method, Troponin submit (21 CFR 862.1215)
CTNI Sample Diluent	No FDA classification

3. Identification of the Predicate Device

Dimension Vista® CTNI Flex® reagent cartridge, K063756
Dimension Vista® CTNI Sample Diluent, K053577

4. Device Description

The Dimension® TNI 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 TNI method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI® technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated anti-cardiac troponin I monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitizer dye. The second bead reagent (Chemibeads) is coated with a second anti-cardiac troponin I monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form bead-cardiac troponin I-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 cardiac troponin I concentration in the sample.

The CTNI Sample Diluent is a liquid, human serum based product with preservatives.

5. Device Intended Use

The TNI method is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I in human serum and plasma on the Dimension® EXL™ integrated chemistry system with LOCI® module. Measurements of cardiac troponin I are used as an aid in the diagnosis of acute myocardial infarction (AMI) and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

The CTNI Sample Diluent is an in vitro diagnostic product for manual dilution of samples with elevated cardiac troponin I results processed on the Dimension Vista® and Dimension® EXL™ integrated chemistry system with LOCI® module.

6. Summary of the devices technological characteristics

The Dimension® TNI Flex® reagent cartridge has the same technological characteristics as the predicate device. A comparison of features is provided.

Feature	**Predicate Device:** **Dimension Vista® CTNI Flex® reagent cartridge**	**New Device:** **Dimension® TNI Flex® reagent cartridge**
Intended Use	Both devices are for in vitro diagnostic use for the quantitative measurement of cardiac troponin I in human serum and plasma.	
Sample Type	Acceptable sample types are human serum and plasma.	
Assay Range	The Dimension Vista® CTNI method has an assay range of 0.015-40 ng/mL.	The Dimension® TNI method has an assay range of 0.017-40 ng/mL.
Technology	Both devices use LOCI® technology.	
Sample Size	Both devices use a sample volume of 20 µL.	
Reagents and antibody	Both devices use the same liquid reagents and antibody.	
Diluent	Both devices use the CTNI Sample Diluent to manually dilute high samples.	
Instrument	The Dimension Vista® CTNI Flex® is run on the Dimension Vista® analyzer.	The Dimension® TNI Flex® is run on the Dimension® EXL™ system with the LOCI module.

7. Method Comparison to the predicate

A split sample method comparison study was conducted on the Dimension® TNI Flex® vs. the Dimension® Vista CTNI Flex® reagent cartridge using two hundred-and-twenty nine (229) serum and plasma samples. The data was analyzed using least squares linear regression. The resulting regression statistics are shown below.

Slope	1.0325
y-int	-0.0284 ng/mL
r	0.998
n	229

8. Conclusion

Based on a review of the devices technological features and the method comparison study, the Dimension® TNI Flex® reagent cartridge is substantially equivalent to the legally marketed device, the Dimension Vista® CTNI Flex® reagent cartridge.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics, Inc.
c/o Yuk-Ting Lewis
RA & Compliance Manager
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Re: k081643
Trade/Device Name: Dimension® TNI Flex® reagent cartridge
CTNI Sample Diluent
Regulation Number: 21 CFR §862.1215
Regulation Name: Creatine Phosphokinase/Creatine Kinase or Isoenzymes Test System.
Regulatory Class: Class II
Product Code: MMI
Dated: June 11, 2008
Received: June 12, 2008

Dear Ms. Lewis:

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); 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 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): K081643

Device Name: Dimension® TNI Flex® reagent cartridge
CTNI Sample Diluent

Indications For Use:

Method
The TNI method is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I in human serum and plasma on the Dimension® EXL™ integrated chemistry system with LOCI® module. Measurements of cardiac troponin I are used as an aid in the diagnosis of acute myocardial infarction (AMI) and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

Diluent
The CTNI Sample Diluent is an in vitro diagnostic product for manual dilution of samples with elevated cardiac troponin I results processed on the Dimension Vista® and Dimension® EXL™ integrated chemistry system with LOCI® module.

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) K081643