JUL - 7 2008

510(k) Summary of Safety and Effectiveness
LOCI® Cardiac Troponin I Calibrator

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: K081683

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 12, 2008

2. Proprietary Device Name / FDA Classification Name

LOCI® Cardiac Troponin I Calibrator / 21 CFR 862.1150

3. Identification of the Predicate Device

Dimension Vista® Cardiac Troponin I Calibrator, K053577

4. Device Description

The LOCI® Cardiac Troponin I Calibrator is a liquid, frozen, human serum based product containing native human troponin complex with other components designed to stabilize the product. The calibrator levels and their nominal values are:

	Level 1	Level 2	Level 3	Level 4	Level 5
TNI	0.00 ng/mL	0.60 ng/mL	6.00 ng/mL	20.00 ng/mL	43.00 ng/mL

5. Device Intended Use

The LOCI® TNI CAL is an in vitro diagnostic product for the calibration of the Cardiac Troponin I (TNI) method on the Dimension® EXL™ integrated chemistry system with LOCI® module.

6. Summary of the devices technological characteristics

A comparison of the LOCI® Cardiac Troponin I Calibrator vs. the predicate device is provided.

Feature	Predicate Device: Dimension Vista® Cardiac Troponin I Calibrator	New Device: LOCI® Cardiac Troponin I Calibrator
Intended Use	The CTNI CAL is an in vitro diagnostic product for the calibration of Cardiac Troponin I (CTNI) on the Dimension Vista system.	The LOCI® TNI CAL is an in vitro diagnostic product for the calibration of the Cardiac Troponin I (TNI) method on the Dimension® EXL™ integrated chemistry system with LOCI® module.
Analyte	Human troponin complex	
Matrix	Human serum	
Form	The calibrators are in a liquid, frozen form.	
Calibrator levels	The CTNI Calibrator kit contains twelve (12) vials; two at each level. The nominal values are 0, 0.4, 4, 8, 20, and 41 ng/mL.	The LOCI® TNI Calibrator kit contains ten (10) vials; two vials at each level. The nominal values are 0.00, 0.60, 6.00, 20.00, and 43.00 ng/mL.
Stability	The stability of the calibrators is established through real-time data on 3 lots of product. Testing is conducted at multiple time points and must pass pre-defined acceptance criteria.	
Traceability	The calibrator is traceable to an internal master pool containing human cardiac troponin complex.	

7. Conclusion

Based on a review of the devices technological features, the LOCI® Cardiac Troponin I Calibrator is substantially equivalent to the legally marketed device, the Dimension Vista® Cardiac Troponin I Calibrator.

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
P.O. Box 6101, M/S 514
Newark, DE 19714

JUL - 7 2008

Re: k081683
Trade/Device Name: LOCI® Cardiac Troponin I Calibrator
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: June 13, 2008
Received: June 17, 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): K081683

Device Name: LOCI® Cardiac Troponin I Calibrator

Indications For Use:

The LOCI® TNI CAL is an in vitro diagnostic product for the calibration of the Cardiac Troponin I (TNI) method on the 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) K081683