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K063243

DEC 1 4 2007

510(k) SUMMARY

VIDAS® Troponin I Ultra (TNIU) Assay

A. Submitter Information

Submitter's Name: Address:	bioMérieux, Inc. 595 Anglum Road Hazelwood, MO 63042
Contact Person:	Nikita S. Mapp
Phone Number:	314-731-7474
Fax Number:	314-731-8689
Date of Preparation:	August 11, 2006

B. Device Name

Trade Name:	VIDAS® Troponin I Ultra (TNIU) Assay
Common Name:	Troponin I Enzyme Immunoassay
Classification Name:	21 CFR 862.1215, Product Code MMI Immunoassay method, Troponin Subunit

C. Predicate Device Name

Trade Name:	Dimension RxL® Cardiac Troponin I (CTNI) Assay

D. Device Description

The VIDAS Troponin I Ultra (TNIU) Assay is an enzyme-linked fluorescent immunoassay (ELFA) performed in an automated VIDAS® instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as the solid phase as well as a pipettor for the assay. Reagents for the assay are in the sealed TNIU Reagent Strips.

The sample is transferred into the wells containing anti-cardiac troponin I antibodies labeled with alkaline phosphatase (conjugate). The sample/conjugate mixture is cycled in and out of the SPR for a specified length of time. Troponin I present in the specimen will bind to the anti-cardiac troponin I immunoglobulin coating the interior of the SPR. Unbound sample components are washed away.

bioMerieux, Inc. • 595 Anglum Road • Hazelwood MO 63042 • Tel: 314 731 8500 • Fax: 314 731 8700
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A fluorescent substrate, 4-methylumbelliferyl phosphate, is introduced into the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The optical scanner in the instrument measures the intensity of fluorescence. When the VIDAS TNIU assay is completed, the results are analyzed automatically by the computer, a test value is generated, and a report is printed for each sample.

E. Intended Use

VIDAS Troponin I Ultra (TNIU) Assay is an automated quantitative test for use on the VIDAS instruments for the determination of human cardiac troponin I in serum or plasma (lithium heparinate) using the ELFA (Enzyme-Linked Fluorescent Assay) technique.

F. Technological Characteristics Summary

Similarities		
Item	**VIDAS® TNIU**	**Dimension RxL® CTNI**
Assay Principle	One-step automated immunoassay based on sandwich principle	Same
Intended Use	Quantitative determination of human cardiac troponin I in human serum or plasma (lithium heparinate)	Same
Indications for Use	An aid in the diagnosis of mycocardial infarction	Same
Sample Type	Human serum or plasma (lithium heparin)	Same
Antibody	Capture: mouse monoclonal antibody Conjugate: mouse monoclonal antibody labeled with alkaline phosphatase	Same

Differences		
Item	**VIDAS® TNIU**	**Dimension RxL® CTNI**
Solid Phase	Solid Phase Receptacle (SPR)	Chrome
Final Detection of troponin-I antigen	Fluorescence (ELFA) of 4-methyl-umbelliferyl measured at 450 nm	Colorimetric rate measurement at 510 nm
Measurement range	0.01 to 30 µg/L	0.04 to 40 µg/L
Analytical Detection Limit	0.01 µg/L	0.04 µg/L
Hook effect	No hook effect found up to concentrations of 1000 µg/L	No hook effect found up to concentrations of 1800 µg/L
Sample Volume	200 µl	50 µl
Assay Time	~20 minutes	~17 minutes

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G. Performance Data

Nonclinical Testing

	Dimension® RxL CTNI	VIDAS® TNIU
Expected Values	97.5% of 101 apparently healthy patients had values of 0.00 -0.05 µg/L	99% of 747 patients with no cardiac symptoms had values of <0.01 µg/l
Cut-off	0.6-1.5 ng/mL	0.11 µg/l
Specificity		
Cardiac Troponin T	1000 µg/L: 0.34%	1000 µg/L: 0.2%
Cardiac Tropponin C	1000 µg/L: 0.00%	1000 µg/L: <0.001
Skeletal Troponin I	1000 µg/L: 0.04%	1000 µg/L: <0.001
Analytical Detection Limit	0.04 µg/L	< 0.01 µg/l
Dilution – Recovery Test	98.6-106.4%	80-120%
Interference	No significant interference	No significant interference
Bilirubin	20 mg/dL	510 µM
Hemoglobin	1000 mg/dL	332 µM
Lipemia (triglycerides)	3000 mg/dL	30 mg/ml
Hook Effect	1800 ng/mL	1000 µg/l

Clinical Testing

Five-hundred and thirty-four samples were tested with both the VIDAS® TNIU Assay (Y) and the Dimension RxL ® CTNI Assay (X). Data from the sample comparison study was evaluated with a Passing-Bablok method and correlation coefficient and produced the following results:

Y = 0.42 X
Confidence interval for the slope: 0.38-0.44
Correlation coefficient = 0.97

H. Conclusion

The VIDAS Troponin I Ultra (TNIU) Assay is substantially equivalent to the Dimension RxL® Cardiac Troponin I (CTNI) Assay.

The 510(k) summary includes only information that is also covered in the body of the 510(k). The summary does not contain any puffery or unsubstantiated labeling claims. The summary does not contain any raw data, i.e., contains only summary data. The summary does not contain any trade secret or confidential commercial information. The summary does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 4 2007

bioMérieux, Inc.
c/o Ms. Nikita S. Mapp
Senior Regulatory Affairs Specialist
595 Anglum Road
Hazelwood, MO 63042

Re: k063243
Trade/Device Name: Vidas Troponin I Ultra (TNIU) Assay, Model 30 448
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine Phosphokinase/Creatine Kinase or Isoenzymes Test System.
Regulatory Class: Class II
Product Code: MMI
Dated: September 14, 2007
Received: September 17, 2007

Dear Ms. Mapp:

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): K063243

Device Name: VIDAS Troponin I Ultra (TNIU)

Indication For Use: VIDAS® Troponin I Ultra is an automated quantitative test for use on the VIDAS instruments for the determination of human cardiac troponin I in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. VIDAS Troponin I Ultra is intended to be used as an aid in the diagnosis of myocardial infarction.

Prescription Use ✓ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (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

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