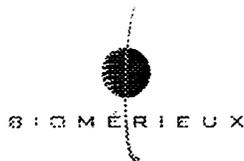


JUN 16 2003

K030950



510(k) SUMMARY

VIDAS Troponin I (TNI) Assay

A. Submitter Information:

Submitter's Name: bioMérieux, Inc.
Address: 595 Anglum Road
Hazelwood, MO 63042

Contact Person: Nancy Weaver
Phone Number: 314-731-8695
Fax Number: 314-731-8689
Date of Preparation: January 17, 2003

B. Device Name:

Trade Name: VIDAS Troponin I (TNI) Assay

Common Name: Enzyme-linked Fluorescent Immunoassay (ELFA) for the quantitative detection of human cardiac troponin I.

Classification Name: 21 CFR 862.1215, Immunoassay method, Troponin Subunit

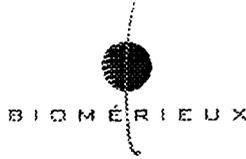
C. Predicate Device Name:

Trade Name: Stratus CS Cardiac Troponin I Testpak

D. Device Description:

The VIDAS Troponin I (TNI) 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 TNI 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.

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 TNI 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 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:

Major Similarities Include:

1. Both tests are run on automated immunoassay systems.
2. Both assays are quantitative tests for the detection of cardiac troponin I in human plasma. The VIDAS assay can also be used with serum.
3. Both test use reagent test strips or packs.
4. Both tests use mouse monoclonal antibodies for antigen capture and in the conjugate.
5. Both assays use 4-methylumbelliferyl phosphate as a fluorescent substrate.

Major Differences Include:

1. The VIDAS TNI assay is a one-step immunoassay sandwich method.
The SCS cTnI assay is two-site sandwich assay based on solid phase Radial Partition Immunoassay technology.
2. The VIDAS TNI assay uses a Solid Phase Receptacle (SPR) to capture the antigen.
The SCS cTnI assay uses glass fiber paper to capture the antigen.



G. Performance Data:

Nonclinical Testing:

	SCS cTnl	VIDAS TNI
Within-run precision: % CV	2.7 – 4.3	1.3 – 2.5
Dilution % Recovery	98.1 – 102.0	97 - 111
Analytical Sensitivity:	0.03 µg/l	< 0.01 µg/l
Expected Values	95% of 101 apparently healthy patients had values of 0.00 - 0.06 µg/l	99.4% of 496 clinically healthy patients had values below 0.1 µg/l
Interference	No significant interference from: Bilirubin 1026 µmol/L Hemoglobin 1000 mg/dL Triglycerides 3000 mg/dL	No significant interference from: Bilirubin 491 µmol/L Hemoglobin 300 µmol/L Triglycerides 30 mg/ml
Specificity:	Troponin-C (cardiac) 1000 µg/l: 0.01%	Troponin C 1000 µg/l: < 0.001%
	Troponin-T (cardiac) 1000 µg/l: 0.04%	Cardiac Troponin T 60 µg/l: 1.6%
	Troponin-T (skeletal) 1000 µg/l: 0.04%	Skeletal Muscle Troponin T 1000 µg/l: < 0.001%
	Troponin-I (skeletal) 280 µg/l: 0.04%	Skeletal Muscle Troponin I 1000 µg/l: < 0.001%

Clinical Testing:

One hundred and seven plasma samples were tested with both the VIDAS TNI (Y) and the SCS Cardiac Troponin I (X). The results are as follows: $Y = 1.016 X - 0.013$ with a correlation coefficient of 0.92.

Thirty-two serum samples were tested with both the VIDAS TNI and the SCS Cardiac Troponin I assay. The results are as follows: VIDAS TNI = 7.33 SCS Cardiac Troponin I
Correlation coefficient = 0.92

H. Conclusion:

The VIDAS Troponin I (TNI) Assay is substantially equivalent to the Stratus CS Cardiac Troponin I Testpak.

bioMérieux, Inc.

595 Anglum Road, Hazelwood, Missouri 63042-2320, USA Phone: 314/731-8500 800/638-4835 Fax: 314/731-8700
<http://www.biomerieux-usa.com>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 16 2003

Ms. Nancy Weaver
Staff Regulatory Specialist
BioMerieux, Inc.
595 Anglum Road
Hazelwood, MO 63042-2320

Re: k030950
Trade/Device Name: VIDAS Troponin I Assay
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatin kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: March 12, 2003
Received: March 26, 2003

Dear Ms. Weaver:

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.

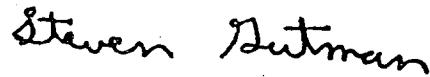
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

Page 2 –

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 (301) 594-3084. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

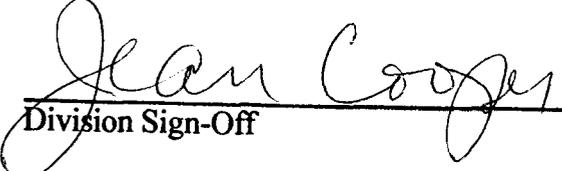
Indications for Use

510(k) Number (if known): _____

Device Name: VIDAS Troponin I Assay

Indications for Use:

VIDAS Troponin I 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



Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K030950

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)