DEC 15 2005

K051433

510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1900 and CFR 807.92.

The assigned 510(k) number is:

Summary prepared on: Sep 10, 2005

Submitted by:
i-STAT Corporation
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E. Windsor, NJ 08520
Phone: 609-443-9300 FAX: 609-443-9310

Contact:
Mike Zelin
Vice-President, R&D
i-STAT Corporation
104 Windsor Center Drive
East Windsor, NJ 08520
Phone: 609-443-9300 Fax: 609-443-9310

Establishment Registration Number: 2245578

Identification of Device:
Device Name: CK-MB Test
Proprietary/Trade Name: i-STAT® CK-MB Test
Common Name: CK-MB, Creatine Kinase MB Isoenzymes
Device Classification: II
Regulation Number: 21 CFR§ 862.1215
Panel: Biosensor, Immunoassay, Cpk Or Isoenzymes
Product Code: MYT

Identification of the Predicate Device:
Device Name: CK-MB test, Triage Cardiac Panel for use on the Triage Meter.

Intended Use of the Device:
The i-STAT CK-MB test is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB in whole blood or plasma samples. CK-MB measurements can be used as an aid in the diagnosis of myocardial infarction (MI).

The cartridge is to be used with the i-STAT 1 Analyzer bearing the (Immuno) symbol, but not with the i-STAT Portable Clinical Analyzer or the Philips Medical Systems (formerly Agilent Technologies) Blood Analysis Module (BAM). As part of the i-STAT System, the CK-MB test is to be used by trained health care professionals in accordance with a facility's policies and procedures.

Description of the Device:
The i-STAT CK-MB test is contained in a single-use test cartridge. In use, the user scans a bar code and then places approximately 16 uL of whole blood or plasma in the cartridge. After the cartridge is closed, it is inserted into the thermally controlled i-STAT 1 Analyzer, and all analytical steps are performed automatically. Patient and use information may be entered into the analyzer via a keypad during the automated analysis cycle.

As the analyzer performs several quality checks and controls the temperature of the sensors via resistive heating to the underside of the sensor chips, the substrate/wash fluid is released into a conduit within the cartridge and a metered volume of the sample over the sensor chips. The enzyme-linked antibody conjugate dissolves into the sample and the sample incubates for a controlled time. The sample is then pushed into a waste chamber and the substrate/wash solution is brought over the sensors. The alkaline phosphatase captured on the CK-MB sensor cleaves the substrate present in the substrate/wash fluid, giving rise to an amperometric signal which is measured.

Comparison to Technological Features of the Predicate Device:
The followig is a comparison of technological features of the i-STAT and Triage Cardiac Panel CK-MB methods:

Characteristic	Triage CK-MB	i-STAT CK-MB
Assay methodology	Two-site ELISA	Two-site ELISA
Capture site	Heterogeneous	Heterogeneous
Capture antibodies	Monoclonal	Monoclonal
Enzyme label antibody	Polyclonal	Monoclonal
Enzyme label	Fluorescent dye	Alkaline phosphatase
Analysis sequence	Simultaneous capture/label	Simultaneous capture/label
Analysis time	16 minutes	5 minutes
Sample type	Whole blood or plasma	Whole blood or plasma
Enzyme detection	Fluorescent	Electrochemical

Summary of Non-Clinical Performance in Support of Substantial Equivalence:

- Studies established that the i-STAT CK-MB test is insensitive to hematocrit levels from 0 to 70 %PCV.
- The CK-MB assay is not significantly influenced by the presence of CK-BB at 100 ng/mL or CK-MM at 10,000 ng/mL.
- Studies established that the interference effects from common medications, particularly those commonly prescribed to patients with cardiovascular conditions, were similar to the effects for those drugs on CK-MB of the Triage Cardiac Panel.
- Studies established that the lower limit of detection (LLD) for the i-STAT method is a comparable 0.6 ng/mL versus 1.0 ng/mL for the CK-MB of the Triage Cardiac Panel.
- The imprecision of the i-STAT CK-MB test using plasma controls was established using in-house and user studies. The Level 1 control %CV was 11.9% at 5.9 ng/mL, the Level 2 control %CV was 10.4% at 25.8 ng/mL and the Level 3 control %CV was 10.0% at 90.1 ng/mL. This includes within-lot, lot-to-lot, vial-to-vial, analyzer-to-analyzer and operator-to-operator components of the imprecision.

Summary of Clinical Test Performance is Support of Substantial Equivalence Claims:
Studies conducted at clinical sites compared the results of the i-STAT CK-MB test to those of the CK-MB test on the Triage Cardiac Panel for samples from patients who presented to the hospital with chest pain. Heparinized whole blood and plasma samples were analyzed on the i-STAT System while plasma samples were analyzed on the Abbott AxSYM. The methods were compared using Deming regression analysis. The results are summarized in the table below:

Statistic	Definition	i-STAT whole blood and plasma vs Abbott AxSYM plasma	
		all samples	samples where [CK-MB] <20.0 ng/mL
N	The number of patient samples included in the data set	263	234
Mean	The average of the comparative method result over the sample population	10.82	3.58
Range	The range of comparative method results obtained over the sample population	0.04 - 224	0.04-15.05
Sxx	The pooled estimate of the within-sample standard deviation of the comparative method over the sample population	1.84	0.34
Syy	The pooled estimate of the within-sample standard deviation of the test method over the sample population	2.66	0.38
Slope	The Deming slope of the correlation	0.1.01	0.993
Intercept	The Deming intercept of the correlation	-0.19	-0.05
Correlation	The correlation coefficient determined from regression	0.994	0.960
Sy.x	The standard error of the estimate of the regression of the regression of y (test method) on x (comparative method) calculated using the regular regression slope	3.98	0.94

Conclusions:
Based on clinical and non-clinical data the i-STAT CK-MB test is insensitive to hematocrit level from 0 – 70 %PCV, is not significantly influenced by the presence of other CK isoforms, shows similar interference effects to common drugs as the CK-MB test on the Triage Cardiac Panel, and has a lower limit of detection (LLD) of 0.6 ng/mL than the CK-MB test on the Triage Cardiac Panel. Studies using plasma controls indicate adequate imprecision for low, mid-range, and high results. Clinical data indicates acceptable correlation to the predicate device.

Identification of Device:

Proprietary/Trade Name: i-STAT® cTnI Test
Name: Immunoassay Method, Troponin Subunit
Device Classification: II
Regulation Number: 21 CFR§ 862.1215
Product Code: MMI

Conclusions:
Based on comparative data the i-STAT TnI test can be run on both heparanized and non-heparanized whole blood samples as contrasted with the original restriction to heparanized whole blood samples (along with plasma samples) as per the current indications for use statement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 15 2005

Ms. Sue Kent
Manager, Clinical Affairs
i-STAT Corporation
104 Windsor Center Drive
East Windsor, NJ 08520

Re: k051433
Trade/Device Name: i-STAT CK-MB test
i-STAT Cardiac Troponin I test
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MYT, MMI
Dated: November 26, 2005
Received: November 29, 2005

Dear Mr. Zelin:

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.

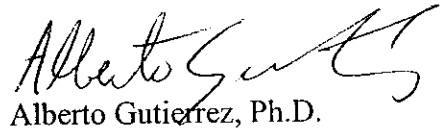
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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) 276-0484. 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/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051433 (previously K031739)

Device Name: i-STAT Cardiac Troponin I test

Indications For Use:

The i-STAT Cardiac Troponin I (cTnI) test is an in vitro diagnostic test for the quantitative measurement of cardiac troponin I in whole blood or plasma. Measurements of cardiac troponin I are used in the diagnosis and treatment of myocardial infarction and as an aid in the risk stratification of patients with acute coronary syndromes wit respect to their relative risk of mortality.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K051433

Indications for Use

510(k) Number (if known): K051433

Device Name: i-STAT CK-MB test

Indications For Use:

The i-STAT CKMB test is an in vitro diagnostic test for the quantitative measurement of creatinine kinase MB mass in whole blood or plasma samples. CK-MB measurements can be used as an aid in the diagnosis and treatment of myocardial infarction (MI).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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