DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

MAY 16 2011

Mitsubishi Chemical Medience Co.
c/o Ms. Judi Smith, LLC
Principal
PO Box 103
Baldwin, MD 21013

Re: k100130
Trade Name: PATHFAST® cTnI-II test; PATHFAST cTnI Calibrators
Regulation Number: 21 CFR §862.1215
Regulation Name: Creatine Phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Codes: MMI, JIT
Dated: May 5, 2011
Received: May 11, 2011

Dear Ms. Smith:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
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): K100130

Device Name: PATHFAST® cTnI-II test

Indication For Use:

PATHFAST® cTnI-II test is an in vitro diagnostic test for the quantitative measurement of cardiac Troponin I (cTnI) in heparinized or EDTA whole blood and plasma. Measurements of cardiac Troponin I are used as an aid in the diagnosis of acute myocardial infarction. This method is for use in clinical laboratory or point of care (POC) settings.

Prescription Use ___X___ 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

510(k) K100130

Indication for Use

510(k) Number (if known): K100130

Device Name: PATHFAST® cTnI Calibrators

Indication For Use:

The PATHFAST® cTnI Calibrators are for calibration of the PATHFAST® system when used for the quantitative determination of cardiac Troponin I in human heparinized or EDTA whole blood and plasma.

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) K100130

PRECISION FOR MEDICINE

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VIA FEDERAL EXPRESS
AND ELECTRONIC TRANSMISSION

January 29, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

ATTN: Courtney H. Lias, PhD, Director, Division of Chemistry and Toxicology Devices

Re: 510(k) Add-To-File for Revised 510(k) Summary and Product Insert
PATHFAST CTNI-II TEST, PATHFAST CTNI CALIBRATORS, PATHFAST SAMPLE DILUENT 2 (K100130)
LSI Medience Corporation

Dear Dr. Lias,

This submission is in regards to the above referenced 510(k) Premarket Notification, PATHFAST CTNI-II TEST, PATHFAST CTNI CALIBRATORS, PATHFAST SAMPLE DILUENT 2 (K100130), cleared May 16, 2011.

We are requesting FDA replace the 510(k) Summary on file for K100130 with the attached 510(k) Summary due to two typographical errors found on page 4 of the 510(k) Summary originally provided to FDA. Specifically, in the section entitled, "Diagnosis of AMI-Serial Samples," in the first table describing the results for the 0.029 ng/mL Cutoff, the 95% confidence intervals for Clinical Sensitivity for the 2 to 6 hour and the 6 to 12 hour collection times were incorrectly reported. These errors have been corrected in the attached revised 510(k) Summary. The following table shows the corrections highlighted in yellow.

Revised 510(k) Summary Table
for Diagnosis of AMI – Serial Samples

			#/TOTAL	95% CI
Cutoff 0.029 ng/mL	0 to 2 h	Sens	73.6% (53/72)	(61.9% - 83.3%)
		Spec	92.7% (242/261)	(88.9% - 95.6%)
	2 to 6 h	Sens	93.1% (67/72)	(84.5% - 97.7%)
		Spec	93.1% (243/261)	(89.3% - 95.9%)
	6 to 12 h	Sens	91.7% (66/72)	(82.7% - 96.9%)
		Spec	91.6% (239/261)	(87.5% - 94.6%)

Please note that all information included within the original 510(k) submission that was reviewed and cleared by FDA was accurate and correctly reported. Thank you for your assistance in this matter.

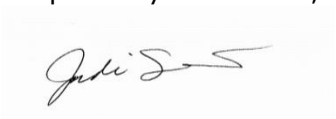
This 510(k) Add-to-File is being provided in duplicate, via one hard copy and one eCopy. The eCopy is an exact duplicate of the paper copy.

Confidentiality

We request that this 510(k) Add-to-File, including commercial information, be maintained by FDA in confidence pursuant to 21 CFR 807.95 for the maximum period allowed by 21 CFR 807.95(b) and (c), and including the maximum post-determination period specified in 21 CFR 807.95(e). Please notify me directly of any request for release of information pertaining to this 510(k) prior to public disclosure of such information.

Please contact the undersigned at (240) 316-3377 or Judi.Smith@precisionformedicine.com if any additional information is required.

Respectfully Submitted,



Judi Smith, MS, MT (ASCP)
Vice President, In Vitro Diagnostics and Quality
Precision for Medicine

For: LSI Medience Corporation

January 29, 2015

510(k) SUMMARY

CONTACT:

Judi Smith
Precision for Medicine
2 Bethesda Metro Center, Suite 850
Bethesda, MD 20814

NAME OF DEVICE:

Trade Name:	PATHFAST® cTnI-II Test, PATHFAST® cTnI Calibrators, PATHFAST® Sample Diluent 2
Common Names/Descriptions:	Cardiac troponin immunoassay
Classification Name:	Immunoassay method, troponin subunit

PREDICATE DEVICE: Siemens Stratus CS Acute Care Troponin I Testpak

DEVICE DESCRIPTION:

INTENDED USE:

PATHFAST cTnI-II test is an in vitro diagnostic test for the quantitative measurement of cardiac Troponin I (cTnI) in heparinized or EDTA whole blood and plasma. Measurements of cardiac Troponin I are used as an aid in the diagnosis of acute myocardial infarction. This method is for use in clinical laboratory or point of care (POC) settings.

The PATHFAST cTnI Calibrators are for calibration of the PATHFAST system when used for the quantitative determination of cardiac Troponin I in human heparinized or EDTA whole blood and plasma.

PATHFAST SAMPLE DILUENT 2 is an in vitro diagnostic product used to dilute samples when PATHFAST assay values exceed the reportable assay range.

DESCRIPTION:

The PATHFAST cTnI-II assay is for the quantitative measurement of human cardiac troponin I in heparinized or EDTA whole blood or plasma. The assay is designed for use on the PATHFAST instrument.

The PATHFAST cTnI-II test is a chemiluminescent enzyme immunoassay performed on the PATHFAST instrument. Patient samples, whole blood or plasma, are dispensed by the operator into the designated area on the reagent cartridge. The instrument combines the patient sample, the antibody coated magnetic particles, and the alkaline phosphatase conjugate and incubates the mixture for 5 minutes at 37°C. During this incubation, the analyte in the patient sample binds to the antibody on the

coated particles, and the alkaline phosphatase conjugate binds to the analyte-antibody-coated particle.

After the incubation, the instrument performs Bound/Free (B/F) separation using Magtration® technology to remove any excess unbound reagents. The chemiluminescent substrate is then added. The substrate is catalyzed by the bound alkaline phosphatase, which results in emission of photons.

The photo-multiplier tube in the PATHFAST instrument detects the photons that are emitted during the reaction. The chemiluminescent count is converted to analyte concentration values by the instrument based on the master calibration curve for the reagent lot.

SUBSTANTIAL EQUIVALENCE:

The PATHFAST cTnI-II assay is substantially equivalent to the Stratus CS cTnI TestPak (predicate device – K033487). The following table summarizes the similarities and differences.

Comparison between PATHFAST cTnI-II and predicate device

	PATHFAST cTnI-II	**Stratus CS cTnI TestPak**
Intended Use	An in vitro diagnostic test for the quantitative measurement of cardiac Troponin I (cTnI) in heparinized or EDTA whole blood and plasma. The PATHFAST cTnI Calibrators are for calibration for the PATHFAST system when used for the quantitative determination of cardiac Troponin I in human heparinized or EDTA whole blood and plasma.	An in vitro diagnostic test for the measurement cardiac Troponin I in heparinized plasma.
Indications for Use	PATHFAST cTnI-II is an in vitro diagnostic test for the quantitative measurement of cardiac Troponin I (cTnI) in heparinized or EDTA whole blood and plasma. Measurements of cardiac Troponin I are used as an aid in the diagnosis of acute myocardial infarction. This method is for use in clinical laboratory or point of care (POC) settings.	The Stratus® CS Acute Care™ Troponin I method is an in vitro diagnostic test for the measurement of cardiac Troponin I in heparinized plasma. Cardiac Troponin I measurements can be used as an aid in the diagnosis of myocardial infarction. Cardiac Troponin I can also be used as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.
Sample type	Plasma, Whole blood	Plasma
Anticoagulant	Heparin, EDTA	Heparin
Calibration	Reagent lot: Initially by master calibration code, then by user with enclosed calibrators. Recalibration required every four weeks	Reagent lot: Initially by master calibration code, then by user with recommended calibrators. Recalibration recommended every 60 days
Controls	Recommended	Recommended
Storage	2 - 8ºC	2 - 8ºC
Test Methodology	Chemiluminescent enzyme immunoassay	Sandwich-type immmunofluorometric assay

	PATHFAST cTnI-II	Stratus CS cTnI TestPak
Reportable range	0.019 – 50 ng/mL	0 – 50 ng/mL
Precision	Whole blood across instruments/within lot %CV from 0.5% to 6.0% with concentrations from 0.096 to 38.5 ng/mL and across lots/within instrument %CV from 1.9% to 9.1% with concentrations from 0.096 to 41.3 ng/mL Plasma across instruments/within lot %CV from 4.3% to 8.0% with concentrations from 0.146 to 30.4 ng/mL and across lots/within instrument %CV from 1.6% to 10.8% with concentrations from 0.157 to 29.7 ng/mL Plasma cutoff within-run %CV from 3.7% to 6.2% and total %CV from 3.9% to 7.1% with concentrations from 0.022 to 0.251 ng/mL	Within run %CV from 2.7% to 4.3% and total %CV from 3.4% to 5.1% with concentrations from 0.64 to 6.48 ng/mL
Limit of blank	0.004 ng/mL	<0.03 ng/mL (analytical sensitivity)
Interfering substances	No interference observed with Bilirubin-conjugated and free (60 mg/dL); Hemoglobin (1000 mg/dL); Triglyceride (1000 mg/dL); Rheumatoid factor (500 IU/mL)	No interference observed with Bilirubin-icterus (60 mg/dl); Hemoglobin (1000 mg/dl); Triglyceride (3000 mg/dl)
Cross reactivity	No significant cross reactivity with cTnT (0.08%); cTnC (0.08%); skTnI (0.09%)	No significant cross reactivity with cTnT (1000 ng/mL); cTnC (1000 ng/mL); skTnI (280 ng/mL)
Reference interval	490 heparinized plasma samples from apparently healthy individuals. 99^{th} percentile = 0.029 ng/mL	101 heparinized plasma samples from apparently healthy individuals. 99^{th} percentile = 0.00 – 0.07 ng/mL
Comparison with predicate	Comparison with predicate device 57 samples from 0.100 to 43.45 ng/mL. y = 0.947x – 0.005, r = 0.994	(With Stratus CS STAT cardiac Troponin I Assay) 168 samples from 0.00 to 34.38 ng/mL. y = 0.96x – 0.11, r = 0.99

Diagnosis of AMI – Serial Samples

An additional study was performed on prospectively collected banked serial plasma samples (heparin anticoagulant) from 333 consecutively eligible consented patients presenting to the ER with suspicion of myocardial infarction (MI). The study yielded 72 MI patients and 261 non-MI patients. The blood sample collection times were at 0-2 hours, at 2 to 6 hours, and at 6 to 12 hours of presentation to the ER. The clinical diagnosis of MI was performed by an adjudication panel according to ESC/ACCF/AHA/WHF 2007 guidelines. The adjudication panel used existing clinical data including ECG and other clinical information to make the diagnosis, but not the final discharge diagnosis or the PATHFAST cTnI-II Test results. Clinical sensitivity and clinical specificity were calculated by comparing the PATHFAST cTnI-II Test results to clinical diagnosis assigned by the adjudication panel. The calculations were performed with both the 99^{th} percentile cutoff (≥0.029 ng/mL) and the ROC cutoff (≥0.264 ng/mL) of the assay.

			#/TOTAL	95% CI
Cutoff 0.029 ng/mL	0 to 2 h	Sens	73.6% (53/72)	(61.9% - 83.3%)
		Spec	92.7% (242/261)	(88.9% - 95.6%)
	2 to 6 h	Sens	93.1% (67/72)	(84.5% - 97.7%)
		Spec	93.1% (243/261)	(89.3% - 95.9%)
	6 to 12 h	Sens	91.7% (66/72)	(82.7% - 96.9%)
		Spec	91.6% (239/261)	(87.5% - 94.6%)

			#/TOTAL	95% CI*
Cutoff 0.264 ng/mL	0 to 2 h	Sens	23.6% (17/72)	(14.4% - 35.1%)
		Spec	99.2% (259/261)	(97.3% - 99.9%)
	2 to 6 h	Sens	62.5% (45/72)	(50.3% - 73.6%)
		Spec	98.1% (256/261)	(95.6% - 99.4%)
	6 to 12 h	Sens	80.6% (58/72)	(69.5% - 88.9%)
		Spec	97.7% (255/261)	(95.1% - 99.2%)

Limitations of procedure

1. The instrument reporting system contains error codes to warn the operator of specific malfunctions. Any reports slip containing such error codes should be kept for follow-up. See the PATHFAST operator's manual.
2. When using the 99th percentile cutoff, the PATHFAST cTnI-II Test should be interpreted with at least 2 serial samples. When using the ROC cutoff, the test should be interpreted with 3 serial samples. When samples are collected in the early hours, it is not advisable to use the higher cutoff.
3. Patient samples may contain heterophilic antibodies that could react in immunoassays to give a falsely high or low result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination of this interference from all patient specimens cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.