DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Mitsubishi Kagaku Iatron Inc.
c/o Judi Smith, LLC
P.O Box 103
Baldwin, MD 21013

SEP 17 2010

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

Re: k081360
Trade/Device Name: PATHFAST CK-MB-II, PATHFAST MYO-II
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: JHX, DDR, JIT
Dated: July 30, 2009
Received: Aug. 4, 2009

Dear Ms. Smith:

This letter corrects our substantially equivalent letter of August 17, 2009.

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 (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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

Indications for Use

510(k) Number (if known): K081360

Device Name: PATHFAST CK-MB-II, and Myo-II tests

Indications For Use:

PATHFAST CK-MB-II test is an in vitro diagnostic test for the quantitative measurement of creatine kinase-MB in heparinized or EDTA whole blood and plasma. Measurements of CK-MB are used in the aid of diagnosis of acute myocardial infarction. This method is for use in clinical laboratory or point of care (POC) settings. The kit includes the reagent cartridges and calibrators.

PATHFAST Myo-II test is an in vitro diagnostic test for the quantitative measurement of myoglobin in heparinized or EDTA whole blood and plasma. Measurements of myoglobin are used to assist in the aid of diagnosis of myocardial infarction (MI). This method is for use in clinical laboratory or point of care (POC) settings. The kit includes the reagent cartridges and calibrators.

Prescription Use ___√____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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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Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K081360