K111452

510(k) Summary

DEC - 9 2011

Submitter's name:	Critical Diagnostics
Address:	3030 Bunker Hill St., Ste 115A San Diego, CA 92109
Phone:	(858) 270-2400
Fax number:	(866) 715-8009
Email:	jsnider@criticaldiagnostics.com
Name of contact person:	James V. Snider

Date the summary was prepared: December 7, 2011

Name of the device:	Presage® ST2 Assay
Trade or proprietary name:	Presage® ST2 Assay
Common or usual name:	ST2 Assay
Classification name:	B-type natriuretic peptide test system
Classification	2
Product Code	OYG, ST2 Assay, JJX, Quality Control Material

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
k093758	Galectin-3 Assay	BG-Medicine

Indication for Use:

The Critical Diagnostics Presage® ST2 Assay kit is an *in vitro* diagnostic device that quantitatively measures ST2 in serum or plasma by enzyme-linked immunosorbant assay (ELISA) in a microtiter plate format. The Presage® ST2 Assay is indicated to be used in conjunction with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure.

The Presage® ST2 Assay Kit Controls, Level 1 and Level 2, are designed to be used for monitoring the performance of test procedures on the Critical Diagnostics Presage® ST2 Assay kit.

Substantial Equivalence

The device and test method contained within the premarket notification and described in the labeling is within a generic type of device described under 21 CFR section 862.1117 and is substantially equivalent to other devices legally marketed in the United States such as the BG Medicine Galectin-3 Assay (k093758).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Critical Care Diagnostics, Inc
c/o James Snider, Ph.D.
3030 Bunker Hill St., Ste 115A
San Diego, CA 92109

DEC - 9 2011

Re: k111452
Trade Name: Presage® ST2 Assay Kit, Presage ST2 Assay Kit Controls
Regulation Number: 21 CFR §862.1117
Regulation Name: B-type Natriuretic Peptide test system
Regulatory Class: Class II
Product Codes: OYG, JJX
Dated: December 5, 2011
Received: December 6, 2011

Dear Dr. Snider:

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 Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k111452

Device Name: Presage® ST2 Assay by Critical Diagnostics

Indications for Use:

The Critical Diagnostics Presage® ST2 Assay kit is an *in vitro* diagnostic device that quantitatively measures ST2 in serum or plasma by enzyme-linked immunosorbant assay (ELISA) in a microtiter plate format. The Presage® ST2 Assay is indicated to be used in conjunction with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure.

The Presage® ST2 Assay Kit Controls, Level 1 and Level 2, are designed to be used for monitoring the performance of test procedures on the Critical Diagnostics Presage® ST2 Assay kit.

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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