K062808

OCT 13 2006

Special 510(k) Summary

510(k)'s Owner Name:	Catch Incorporated
Address:	11822 Northcreek Parkway North, Suite 107 Bothell, WA 98011
Phone Number:	425.402.8960
Fax Number:	425.402.8954
Contact Person:	Glenn Kawasaki
Date of Preparation:	September 15, 2006
Trade Name:	Liquid Stable (LS) 2-Part Homocysteine Reagent
Common Name:	Homocysteine Reagent
Classification Name:	Urinary Homocystine (Nonquantitative) Test System

Device Description:
The Liquid Stable (LS) 2-Part Homocysteine Reagent will consist of two (2) reagents plus calibrators. The first reagent (LS-R1) will include Lactic Acid Dehydrogenase (LDH), Serine, and ß-Nicotinamide Adenine Di-Nucleotide reduced Di-Sodium Salt (NADH) with buffers and stabilizers. The fill volume will be 30 to 50 mL, depending on the kit configuration.

The second reagent (LS-R2) will include Cystathionine B-Synthase (CBS) and Cystathionine B-Lyase (CBL) enzymes with buffers and stabilizers. The fill volume will be 7 mL for all kit configurations.

The calibrators will include two (2) bottles; Calibrator "A" will be 0 µmoles/L and Calibrator "D" will be 25-30 µmoles/L. The fill volume for the calibrators will be 3 mL.

Intended Use:	Intended for the in vitro quantitative determination of total homocysteine in serum and plasma.

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Summary of Technological Characteristics:

	Liquid Stable (LS) 2-Part Homocysteine Reagent	**Homocysteine Enzymic Homocysteine Reagent K011689**	**Comparison**
Intended Use	Intended for the in vitro quantitative determination of total homocysteine in serum and plasma.	Intended for the in vitro quantitative determination of total homocysteine in serum and plasma.	Same
Methodology	Clinical enzymatic chemistry reagents; 2-part reagent	Clinical enzymatic chemistry reagents; 2-part reagent	Same
Specimen type	Serum and plasma	Serum and plasma	Same
Instrumentation	Standard clinical chemistry analyzer	Standard clinical chemistry analyzer	Same
Calibration	Calibrator provided (0 µmoles/L and 25-30 µmoles/L)	Calibrator provided (0 µmoles/L and 25-30 µmoles/L)	Same
Reagent Formulations	Reagent LS R1	R1A, R1B	Different
	Reagent LS R2	R2	Same
	Calibrators	Calibrators	Same
Performance	Correlation coefficient >0.95 (0.997) when compared to current Homocysteine Enzymic Homocysteine Reagent	Correlation coefficient >0.95 (0.993) when compared to Abbott FPIA assay	Same
Precision (within run)	Low – CV 2.3% Mid – CV 1.8% High – CV 1.3%	Low – CV 3.5% Mid – CV 2.5% High – CV 2.1%	Same
Precision (total)	Low – CV 4.3% Mid – CV 2.8% High – CV 2.4%	Low – CV 5.6% Mid – CV 4.7% High – CV 3.8%	Same

Similarities include: Intended use, methodology, specimen type, calibration requirements, and performance. Differences include: Modification of formulation to improve reagent stability of R1 as compared to when Reagent R1A is mixed with Reagent R1B to give R1 in the Homocysteine Enzymic Homocysteine Reagent.

Conclusion based on similarities and differences: Liquid Stable (LS) 2-Part Homocysteine Reagent is substantially equivalent to the Homocysteine Enzymic Homocysteine Reagent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Catch Incorporated
c/o Cindy Green, RAC
Northwest Regulatory Support
P.O. Box 1277
Maple Valley, WA 98038

OCT 13 2006

Re: k062808
Trade/Device Name: Liquid Stable (LS) 2-Part Homocysteine Reagent
Regulation Number: 21 CFR 862.1377
Regulation Name: Urinary homocystine (non-quantitative) test system
Regulatory Class: Class II
Product Code: LPS
Dated: September 29, 2006
Received: October 3, 2006

Dear Mr. Kawasaki:

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): k062808

Device Name: Liquid Stable (LS) 2-Part Homocysteine Reagent

Indications For Use:

Intended for the in vitro quantitative determination of total Homocysteine in serum and plasma to assist in the diagnosis and treatment of patients suspected in having homocystinuria and hyperhomocysteinemia.

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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K062808