FEB 16 2006

K060133

Section 5

510(k) Summary

Submitted by:	James M. Delaney Inverness Medical Innovations, Inc. 51 Sawyer Rd., Ste. 200 Waltham, MA 02453
Prepared on:	January 12, 2006
Device name	The Ischemia Albumin Cobalt Binding Test (ACB® Test) Assay Verification Set
Classification name	Quality Control Material (assayed and unassayed) The Assay Verification Set is classified as Class I, Clinical Chemistry Panel (75), Pro Code JJX-Single (Specified) Analyte Controls (Assayed and Unassayed). The device is codified at 21 C.F.R. § 862.1660.
Predicate Device	Maine Standards Company VALIDATE CHEM 3 Calibration Verification Test Set
Intended Use	The Ischemia ACB® Assay Verification Set is intended for use in verifying accuracy of the ACB Test on the Roche Integra 700/800. It is recommended as a part of assay installation. For *In Vitro* Diagnostic Use.
Technological Characteristics	The Assay Verification Set consists of twenty (20) single vial 0.5 mL aliquots of frozen serum based samples with assigned IMA values over the physiological range.
Testing	The Assay Verification Set was evaluated for expiry date and for range setting values internally and at multiple clinical sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. James M. Delaney
Director Regulatory Affairs
Inverness Medical Innovations, Inc.
51 Sawyer Rd. Suite 200
Waltham, MA 02453-3448

FEB 16 2006

Re: k060133
Trade/Device Name: The Ischemia Albumin Cobalt Binding Test (ACB®) Assay Verification Set
Regulation Number: 21 CFR§ 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: January 16, 2006
Received: January 18, 2006

Dear Mr. Delaney:

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 Statement

Indications for Use

510(k) Number (if known):

Device Name: The Ischemia Albumin Cobalt Binding Test (ACB®) Assay Verification Set

Indications For Use: The Ischemia Albumin Cobalt Binding Test (ACB®) Assay Verification Set is intended for use in verifying accuracy of the ACB Test on the Roche Integra 700/800. It is recommended as a part of assay installation.

For *In Vitro* Diagnostic Use

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)

Ann Chaffee

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060133