DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Peter Crosby,
Ischemia Technologies, Inc.
President and Chief Executive Officer
4600 West 60th Avenue
Denver, CO 80003

FEB 1 4 2003

Re: K023824
Trade/Device Name: Albumin Cobalt Binding Test (ACB® Test)
Regulation Number: 862.1215
Regulation Name: Albumin Cobalt Binding Test
Regulatory Class: Class 2
Product Code: NJV
Dated: 15 November, 2002
Received: 18 November, 2003

Dear Mr. Crosby:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of In Vitro Diagnostic Device Evaluation and Safety has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in patients with potential Acute Coronary Syndrome (ACS) who have positive IMA levels; or positive troponin levels combined with negative, non-diagnostic, or positive ECG; or positive ECG combined with positive or normal troponin levels has not been established. IMA results do not correlate with disease risk in the event of a positive IMA, ECG, or troponin test result, therefore reliance on the IMA results alone could be misleading as either ruling in or ruling out ACS.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 (CFR), Title 21, 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).

If you desire specific information about the application of other 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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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/dsma/dsmamain.html.

Sincerely yours,

S. Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K023824

Device Name: Albumin Cobalt Binding Test (ACB Test)

Indications For Use:

The Albumin Cobalt Binding Test (ACB® Test) is a quantitative in vitro *diagnostic test used on human serum that detects Ischemia Modified Albumin (IMA™) by measuring the cobalt binding capacity of albumin in human serum. IMA is intended for use in conjunction with ECG and cardiac troponin as an aid to the short term risk stratification of patients presenting with chest pain suggestive of cardiac origin.*

Thus, in patients with chest pain or equivalent symptoms suggestive of cardiac origin, with non-diagnostic ECG and normal troponin, a negative IMA can be used as an aid to rule out Acute Coronary Syndromes (ACS) in low risk patients.

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023824