DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 3 - 2003

Vancouver Biotech Ltd.
c/o Ms. Robin J. Hellen, M.S.
Hellen Professional Services
9418 Lasaine Avenue
Northridge, CA 91325

Re: k023505
Trade/Device Name: Vancouver Biotech, Ltd. Rapid Human Cardiac Troponin I Test or Vancouver Biotech, Ltd. Serum Troponin I Test
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: January 24, 2003
Received: January 29, 2003

Dear Ms. Hellen:

This letter corrects the SE letter dated March 31, 2003. The indications for use wording was incorrect. It now reads "The *VBL Serum Troponin I Test* is intended for the qualitative determination of cardiac Troponin I in human serum". The word used before was quantitative. It was changed to qualitative.

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven 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

IV. STATEMENT FOR INDICATIONS FOR USE

510(k) Number (if known): K 023 505

Device Name: *Vancouver Biotech, Ltd.*
Rapid Human Cardiac Troponin I Test
Or VBL Serum Troponin I Test

Indications for Use:

The *VBL Serum Troponin I Test* is intended for the qualitative determination of cardiac troponin I in human serum. Measurement of troponin I values are useful in the evaluation of acute myocardial infarction (AMI).

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over the Counter Use: _____

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K 023 505