OCT 0 8 2002

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K022946

1. Date of Summary: Sept. 3, 2002

2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   PHONE 732-274-1000
   FAX 732-274-1010
   Contact Person: Jemo Kang

3. Device Name: Trade Name: LifeSign MI® Myoglobin/Troponin I
   Myoglobin/Troponin I Rapid Test
   LifeSign® Myoglobin/Troponin I
   BioSign™ MI Myoglobin/Troponin I
   BioSign™ Myoglobin/Troponin I
   VitalSign™ Myoglobin/Troponin I
   VitalSign™ MI Myoglobin/Troponin I
   AccuSign™ Myoglobin/Troponin I
   AccuSign™ MI Myoglobin/Troponin I

   Common Name: Immunoassay for the detection of myoglobin and cardiac troponin I in human serum, whole blood or plasma

   Classification Name: Not found (enzymatic assay and Immunology 82DEA for Myoglobin antigen)

4. Identification of legally marketed device to which claims equivalence: K981882 Cardiac STATus™CKMB/Myoglobin/TroponinI

5. Device Description: LifeSign MI® Myoglobin/Troponin I is simple one step immunochromatographic test for the rapid, qualitative detection of myoglobin and Troponin I.

6. Intended Use: The LifeSign MI® Myoglobin/Troponin I Rapid Test is intended for use as an *in vitro* diagnostic product for the rapid qualitative determination of myoglobin and troponin I in serum, human whole blood, or plasma as an aid in the diagnosis of myocardial infarction in emergency room, critical care, point of care or hospital settings.

7. Substantial Equivalence: LifeSign MI® Myoglobin/Troponin I is substantially equivalent to K981882, Cardiac STATus™ CK-MB/Myoglobin/Troponin I. LifeSign MI® Myoglobin/Troponin I is exactly same as Cardiac STATus™ CK-MB/Myoglobin/Troponin I test except that CK/MB antibodies were removed from Cardiac STATus™ CK-MB/Myoglobin/Troponin I test.

Conclusion: The device is substantially equivalent to the legally marketed device, K981882, Cardiac STATus™ CK-MB/Myoglobin/Troponin I.

Substantial Equivalence

The LifeSign MI® Myoglobin/Troponin I Rapid Test is substantially equivalent to Cardiac STATus™ CK-MB/Myoglobin/Troponin I, k981882, currently in commercial distribution by Princeton BioMeditech Corp. as shown below.

Features	Predicate Devices	Candidate Device
Device	solid phase immuno-chromatographic assay	solid phase immuno-chromatographic assay
Antibodies	antibodies to CK-MB myoglobin and TnI	antibodies to myoglobin and TnI same antibodies as predicate device
Membrane removal of red cells	Yes	Yes
Time to result	15 minutes	15 minutes
Analytes	CK-MB, myoglobin Troponin I	myoglobin Troponin I
Specimens	serum, whole blood, or plasma	serum, whole blood, or plasma
Sample volume	200 µl	200 µl
Visual Reading	Yes	Yes
Storage	Room temperature	Room temperature

Both the predicate device and the candidate device are developed and manufactured by the same applicant of this modification submission. The two devices are made exactly same way (protocol, reagents, chemicals) except that the candidate device does not contain antibodies for the CKMB.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 0 8 2002

Jemo Kang, Ph.D.
President
Princeton BioMeditech Corporation
P.O. Box 7139
Princeton, NJ 08543-7139

Re: k022946
Trade/Device Name: LifeSign MI® Myoglobin/Troponin I Rapid Test
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes system
Regulatory Class: Class II
Product Code: MMI
Dated: September 3, 2002
Received: September 5, 2002

Dear Dr. Kang:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known) : K022946

Device Name : LifeSign MI® Myoglobin/Troponin I Rapid Test

Indications for Use:

The LifeSign MI® Myoglobin/Troponin I Rapid Test is intended for use as an *in vitro* diagnostic product for the rapid qualitative determination of myoglobin and troponin I in serum, human whole blood, or plasma as an aid in the diagnosis of myocardial infarction in emergency room, critical care, point of care or hospital settings.

Jean Cooper

ion Sign-Off)
n of Clinical Laboratory Devices
Number K022946

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Professional Use __X___

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