NOV 2 2 2004

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: K040708

1. Date of Summary: Mar. 16, 2004

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, Ph.D. ext.103

3. Device Name
   Trade Names: Status First™ Strep A
   FDA Classification Name: Immunoassay, Streptococcus SPP. (Microbiology Classification Device List)

4. Identification of legally marketed device to which claims equivalence:
   BioSign StrepA, k971349

5. Device Description: Status First™ Strep A is an *in vitro*, simple, one step immunochromatographic diagnostic test for the rapid, qualitative detection of Group A Streptococcal antigen

6. Intended Use: Status First™ Strep A is an immunoassay for the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens to aid in the early diagnosis of Group A Streptococcal infection.

7. Substantial Equivalence: The Status First™ Strep A test is substantially equivalent in intended use, principle and performance to the current BioSign Strep A test. Both assays are *in vitro* immunochromatographic assays with an intended use as an aid in the early diagnosis of Group A Streptococcal infection.

   There is no formulation change associated with the BioSign Strep A labeling change. The two products are identical and use the same manufacturing processes. Only the sample extraction step is different in the package insert.

Conclusion: The device is substantially equivalent to a legally marketed device, k971349.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 2 2004

Jemo Kang, Ph.D.
President
Princeton BioMeditech Corporation
4242 U.S. Route 1
Monmouth Junction., NJ 08852-1905

Re: k040708
Trade/Device Name: Status First™ Strep A
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcus Spp. Serological Reagents
Regulatory Class: Class I
Product Code: GTY
Dated: October 1, 2004
Received: October 4, 2004

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.

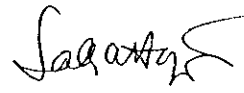
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040708

Device Name: Status First™ Strep A

Indications For Use:

Status First™ Strep A is an immunoassay for the qualitative detection of Group A Streptococcal antigen directly from throat swab specimens to aid in the early diagnosis of Group A Streptococcal infection.

Prescription Use: X AND/OR Over-The-Counter Use: ____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040708