MAY 2 3 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: K020439

1. Date of Summary: Feb.05, 2002

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

3. Device Name: Trade Names: Status hCG™ Serum/Urine
   BioSign™ hCG Serum/Urine

   Common or Usual Name: Immunoassay for detection of Human Gonadotropin in urine

   Classification Name: Immunosassay, human Chorionic Gonadotropin (hCG) (Clinical Chemistry Classification Device List)

4. Identification of legally marketed device to which claims equivalence: QuickVue®hCG Combo Test by Quidel in Sandiego, CA

5. Device Description: Status hCG™ Serum/Urine is simple one step immunochromatographic test for the rapid, qualitative detection of hCG in serum or urine.

6. Intended Use: Immunoassay for in vitro diagnostic use in hospital, clinical laboratories and physician' offices for the qualitative detection of Human Chorionic Gonadotropin (hCG) in serum or urine for the early detection of pregnancy.

7. Substantial Equivalence: Status hCG™ is substantially equivalent to premarketed device QuickVue® hCG Combo Test. Both products use the same immunochromatographic assay to detect hCG in serum or urine qualitatively. The tests demonstrated 100 % correlation when 100 specimens (50 negative and 50 positive) were compared for urine test or for serum test.

Conclusion: The device is as safe, as effective, and performs as well as the legally marketed device QuickVue® hCG-Combo Test by Quidel Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 23 2002

Kyung-ah Kim, Ph.D.
Principal Scientist
Princeton BioMeditech Corporation
4242 U.S. Route 1
Monmouth Junction, NJ 08852 1905

Re: k020439
Trade/Device Name: Status hCG™ Serum/Urine, BioSign™ hCG Serum/Urine
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: April 22, 2002
Received: April 23, 2002

Dear Dr. Kim:

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): K020439

Device Name: Status hCG™ Serum/Urine, BioSign™ hCG Serum/Urine,

Indications For Use:

Immunoassay for in vitro diagnostic use in hospital, clinical laboratories and physician' offices for the qualitative detection of Human Chorionic Gonadotropin (hCG) in serum or urine for the early detection of pregnancy.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020439

(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)