JAN 2 3 2006

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: K050955

1. Date of Summary: Dec.16, 2005

2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   Phone 732-274-1000
   Fax 732-274-1010

3. Device Name
   Trade Names: StatusFirst™ hCG Serum/Urine
   FDA Classification Name: Immunoassay, human Chorionic Gonadotropin (hCG) (Clinical Chemistry Classification Device List)

4. Identification of legally marketed device to which claims equivalence:
   K993065: Icon 25 hCG by Beckman Coulter

5. Device Description: StatusFirst™ hCG Serum/Urine is a qualitative test for the rapid detection of human chorionic gonadotropin (hCG) in serum or urine. The device is used with DXpress™ Reader.

6. Intended Use: StatusFirst™ hCG Serum/Urine test is *in vitro* diagnostic use for a qualitative detection of Human Chorionic Gonadotropin(hCG) in serum or urine for the detection of pregnancy.

7. Subtantial Equivalance: StatusFirst™ hCG Serum/Urine is substantially equivalent to premarketed device Icon 25 hCG test. Both products use the same immunochromatographic assay to detect hCG in serum or urine qualitatively. The tests demonstrated 93% agreement when 116 specimens were compared for urine test or for serum test. The disagreements were shown in the borderline samples. StatusFirst™ hCG Serum/Urine read the borderline samples as borderline level, whereas predicate device read most of borderline samples as positive.
   We may conclude StatusFirst™ hCG Serum/Urine is substantially equivalent to a legally marketed device, K993065, Icon 25 hCG test.

Name of Manufacturer:

Princeton BioMeditech Corporation
4242 U.S. Route 1
Monmouth Junction, New Jersey 08852

Establishment Registration Number:

2246703

Product Name:

Reader

A. Trade Name: LifeSign DXpress™

B. Common or Usual Name:

Reflectance Photometer for clinical use

C. Classification Name:

Colorimeter, photometer, or spectrophotometer for clinical use (Clinical Chemistry and Clinical Toxicology device classification)

hCG test

A. Trade Name: StatusFirst™ hCG Serum/Urine

B. Common or Usual Name:

hCG test system

C. Classification Name:

Immunoassay, human Chorionic Gonadotropin (hCG) (Clinical Chemistry Classification Device List)

Product Classification:

The tentative classification of the device under Section 513 of the Act is made available by the Food and Drug Administration.

Reader

Class: I (General Control)
Panel: Clinical Chemistry and Clinical Toxicology Devices
Product Classification Code: JJQ – Clinical Chemistry
Regulation Number: CFR 862.2300

hCG Test

Class: II (General Control)
Panel: Clinical Chemistry and Clinical Toxicology
Product Classification Code: JHI
Regulation Number: 21CFR 862.1155

Performance Standards:

Princeton BioMeditech Corporation has reviewed the requirement of Section 514 of the Act and has no reason to believe that any performance standards have been established yet for this device.

Subtantial Equivalance (807, 87f)

StatusFirst™ hCG Serum/Urine Test is substantially equivalent to **Icon 25 hCG test (serum and urine use)** which is in commercial distribution by Beckman Coulter, CA.

StatusFirst™ hCG Serum/Urine Test vs. Icon 25 hCG test

Similarities:

1. Both assays measure hCG in urine or serum.
2. Both assays are *in-vitro* immunological assays using immunochromatographic method.
3. Both assays give the result with the colored signal.
5. Both assays are qualitative test.
6. Both assays detect hCG at 25 mIU/mL in serum or urine.

Differences:

1. **StatusFirst™ hCG Serum/Urine Test** read the result by DXpress reader, whereas Icon25 hCG read the result visually.
2. **StatusFirst™ hCG Serum/Urine Test** reads the result at 5 min for both serum and urine samples, whereas Icon25 hCG read the result at 3 min for urine sample and 5 min for serum sample.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 23 2006

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

Re: k050955
Trade/Device Name: LifeSign DXpress™ reader, StatusFirst™ hCG Serum/Urine
Regulation Number: 21 CFR§862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI, JJQ
Dated: December 20, 2005
Received: December 21, 2005

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 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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050955

Device Name: LifeSign DXpress™ reader, StatusFirst™ hCG Serum/Urine

Indications For Use:

1. Reflectance photometer for the measurement of concentration of analyte in various assays manufactured by PBM. The concentration is measured by density of light reflectance.
2. Reflectance photometer for a reading of test signal instead of visual reading in various qualitative assays manufactured by PBM.
3. StatusFirst™ hCG Serum/Urine test is *in vitro* diagnostic use for a qualitative detection of Human Chorionic Gonadotropin(hCG) in serum or urine for the detection of pregnancy.

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)

Ann Chappie
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K050955