FEB 2 0 2007

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: K062565

Date of Summary: August 28, 2006

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: Status DS™ Nicotine, AccuSign® Nicotine
Common or Usual Name: Immunoassay for detection of cotinine, metabolite of nicotine in urine
Classification Name: Carbon monoxide test system (21CFR862.3220, Product Code: MKU)

4. Identification of legally marketed device to which claims equivalence:
k972481; Auto-Lyte Cotinine EIA

5. Device Description: Status DS™ Nicotine is a simple one step immunochromatographic test for the rapid, qualitative detection of cotinine, a major metabolite of nicotine.

6. Intended Use: Status DS™ Nicotine is designed for the qualitative detection of cotinine at the cutoff of 500 ng/mL in urine to assist in screening for exposure to nicotine. For *In vitro* Diagnostic, Professional Use.
The Status DS™ Nicotine test provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography, mass spectrometry (GC/MS) is the preferred confirmatory method.

7. Substantial Equivalence: Status DS™ Nicotine is substantially equivalent to the k972481; Auto-Lyte Cotinine EIA manufactured by Orasure Technologies, Inc. Status DS™ Nicotine is a qualitative test and Auto-Lyte Cotinine EIA is a qualitative and semiquantitative test. Both tests detect cotinine in human urine at the cutoff level of 500 ng/mL. The tests demonstrated 100 % correlation when 94 specimens (50 negative and 44 positive) were compared.

Conclusion: The device is substantially equivalent to a legally marketed device k972481, Auto-Lyte Cotinine EIA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kyung-Ah Kim
Princeton Biomeditech Corp.
4242 U.S. RT. 1
Monmouth Junction, NJ 08852-1905 US

FEB 2 0 2007

Re: k062565
Trade/Device Name: Status DS Nicotine, Accusign Nicotine, Biosign Nicotine
Regulation Number: 21 CFR 862.3220
Regulation Name: Carbon Monoxide test system.
Regulatory Class: Class I, reserved
Product Code: MKU
Dated: January 16, 2007
Received: January 18, 2007

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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): K062565

Device Name: Status DS™ Nicotine

Indications For Use:

Immunoassay for the qualitative detection of cotinine, a major metabolite of nicotine, at the cut-off of 500 ng/mL in human urine. Status DS™ Nicotine is used as an aid in the detection of cotinine after use of tobacco products or other products containing nicotine. For *In vitro* Diagnostic Use

The Status DS™ Nicotine test provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography, mass spectrometry (GC/MS) is the preferred confirmatory method.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K062565

Indications for Use

510(k) Number (if known): K062565

Device Name: AccuSign® Nicotine

Indications For Use:

Immunoassay for the qualitative detection of cotinine, a major metabolite of nicotine, at the cut-off of 500 ng/mL in human urine. AccuSign® Nicotine is used as an aid in the detection of cotinine after use of tobacco products or other products containing nicotine. For *In vitro* Diagnostic Use

The AccuSign® Nicotine test provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography, mass spectrometry (GC/MS) is the preferred confirmatory method.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

K062565