K133474

DEC 10 2013

510(k) Summary

1. **Name and 510k number of the previously cleared device**

   510k Number: K132465
   Trade Name: BioSign® Flu A+B, Status Flu A&B
   Common or Usual Name: Influenza test
   Classification Name: Influenza virus serological reagents (21CFR 866.3330)

2. **Regulatory Class:** I

3. **Product Code:** GNX

4. **Description of the device modification(s):**

   The modification presented in this 510(k) is the addition of influenza A/Vietnam/1194/2004 (H5N1) and influenza A/Anhui/01/2005 (H5N1) along with their respective analytical sensitivity concentrations, to the Analytical Inclusivity section of the package insert.
   The avian influenza A (H5N1) viruses, A/Vietnam/1194/2004 (H5N1) and A/Anhui/01/2005 (H5N1) were obtained from CDC as a non-infectious form with known titer. Analytical sensitivity is reported as the lowest dilution/concentration of the virus that the BioSign®Flu A+B Test is able to detect.

5. **Comparison to the cleared device**

   Below are the similarities and differences between the modified device and the cleared device.

   Similarities

Device Characteristics	**Modified Device**	**Cleared Device K132465**
Intended Use	Same as Cleared device	The BioSign Flu A+B test is an in vitro rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens obtained from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results are presumptive and it is recommended these results be confirmed by viral culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. The test is

		intended for professional and laboratory use. Performance characteristics for influenza were established during the 2007-2009 influenza seasons when influenza A viruses A/New Caledonia/20/99 (H1N1), A/Solomon Islands/3/2006 (H1N1), A/Brisbane/59/2007 (H1N1), A/California/07/2009 (H1N1), A/Wisconsin/67/2005 (H3N2), A/Brisbane/10/2007 (H3N2), and influenza B viruses B/Ohio/01/2005, B/Florida/4/2006, B/Brisbane/60/2008 were the predominant influenza viruses in circulation according to the Flu Activity & Surveillance report by CDC. Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL+3 facility is available to receive and culture specimens.
Sample Type	Same as Cleared device	Nasal swab Nasopharyngeal swab Nasopharyngeal aspirate/wash specimens
Analytical Principle	Same as Cleared device	Solid phase chromatographic immunoassay
Extraction	Same as Cleared device	Incubated for 1 min in the extraction reagent
Result Read time	Same as Cleared device	10 minutes
Test Line	Same as Cleared device	Colloidal gold
Internal Control	Same as Cleared device	Reddish-purple line
Control Samples (supplied as prepared swabs)	Same as Cleared device	Positive Control Swab: Influenza A and B antigens (non-infective recombinant nucleoprotein) Negative Control Swab: Inactivated Group B Streptococcus antigen (non-infective)

Differences

The package insert has been updated to include detection of Influenza A/Vietnam/1194/2004 (H5N1) and Influenza A/Anhui/01/2005 (H5N1) in the analytical reactivity table.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Kyung-ah Kim, Ph.D.
Director Operations/Quality Systems
Princeton BioMeditech Corporation
4242 US Highway 1
Monmouth Junction, NJ 08852

December 10, 2013

Re: K133474
Trade/Device Names: BioSign® Flu A+B
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: I
Product Code: GNX
Dated: November 7, 2013
Received: November 12, 2013

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 the legally marketed predicate device marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to the device that has been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that does 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number: K133474

Device Name: BioSign® Flu A+B

Intended Use: The BioSign Flu A+B test is an *in vitro* rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens obtained from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. Negative test results are presumptive and it is recommended these results be confirmed by viral culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. The test is intended for professional and laboratory use. Performance characteristics for influenza were established during the 2007-2009 influenza seasons when influenza A viruses A/New Caledonia/20/99 (H1N1), A/Solomon Islands/3/2006 (H1N1), A/Brisbane/59/2007 (H1N1), A/California/07/2009 (H1N1), A/Wisconsin/67/2005 (H3N2), A/Brisbane/10/2007 (H3N2), and influenza B viruses B/Ohio/01/2005, B/Florida/4/2006, B/Brisbane/60/2008 were the predominant influenza viruses in circulation according to the Flu Activity & Surveillance report by CDC. Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL+3 facility is available to receive and culture specimens.

Prescription Use X (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 OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Tamara V. Feldblyum -S
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