JUL 7 - 2005

K042472

510(k) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
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CONTACT NAME: Michelle Bytheway Bandy

DATE PREPARED: May 31, 2005

DEVICE TRADE NAME: BD Directigen™ EZ Flu A+B

DEVICE COMMON NAME: Influenza virus serological reagents

DEVICE CLASSIFICATION: 21 CFR§866.3330

PREDICATE DEVICES:
Cell Culture
Direct Fluorescent Antibody (DFA)
BD Directigen™ Flu A+B
Remel Xpect™ FLU A/B

INTENDED USE:

The BD Directigen™ EZ Flu A+B test is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal washes/aspirates and throat swabs of symptomatic patients. The BD Directigen™ EZ Flu A+B test is a differentiated test, and therefore influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. All negative test results should be confirmed by cell culture.

DEVICE DESCRIPTION:

The BD Directigen™ EZ Flu A+B test is a chromatographic assay to qualitatively detect influenza A and B viral antigens in samples processed from respiratory specimens. When specimens are processed and added to the test device, influenza A and/or B viral antigens bind to anti-influenza antibodies conjugated to visualizing particles in the corresponding A and B test strips. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of antibody on the membrane. A positive result is visualized as a reddish purple line at the Test "T" position in the Flu A or Flu B read window in combination with a reddish purple line at the Control "C".

DEVICE COMPARISON:

The BD Directigen™ EZ Flu A+B test was compared to viral cell culture, direct fluorescent antibody (DFA) tests, the BD Directigen™ Flu A+B test (K001364) and the Remel Xpect FLU A/B test (K031565). Although there are some differences between the BD Directigen™ EZ Flu A+B test and the predicate devices, these differences do not present new issues of safety and effectiveness. The impact of these differences on the safety and effectiveness of the BD Directigen™ EZ Flu A+B test was assessed using accepted scientific methods.

SUMMARY OF PERFORMANCE DATA:

ANALYTICAL STUDIES

Comparison studies were conducted to determine analytical sensitivity and specificity as well as evaluate the BD Directigen™ EZ Flu A+B test for potential cross reactivity or interfering substances.

Analytical Sensitivity

The limit of detection (LoD) for the BD Directigen™ EZ Flu A+B test was established for a total of nine influenza A and six influenza B strains. The LoD for the strains tested ranged from 2.78 X 10^2 to 6.95 X 10^5 $CEID_{50}$/mL.

Analytical Specificity

A panel of 37 influenza A and influenza B strains were tested in triplicate with the BD Directigen™ EZ Flu A+B test. All influenza A strains resulted in positive Flu A results and negative Flu B results. Likewise, all influenza B strains resulted in positive Flu B results and negative Flu A results.

Cross Reactivity

A panel of 98 microorganisms (including bacteria, yeasts and viruses) was cultured and tested in triplicate with the BD Directigen™ EZ Flu A+B test. None of the microorganisms tested in the panel were shown to cross react with the BD Directigen™ EZ Flu A+B test.

Interfering Substances

A variety of substances were tested with the BD Directigen™ EZ Flu A+B test in triplicate at concentration levels comparable to or greater than levels that may be present in patient respiratory samples. Substances tested included blood and various medications. None of the substances evaluated were shown to interfere with the performance of the BD Directigen™ EZ Flu A+B test.

CLINICAL STUDIES

Performance characteristics of the Directigen™ EZ Flu A+B test were established over two flu seasons (2003/04 and 2004/05) in a geographically diverse multi-center study.

Reproducibility

The reproducibility of the BD Directigen™ EZ Flu A+B test was evaluated at four sites. The overall reproducibility for the BD Directigen™ EZ Flu A+B test was 99.6%.

Clinical Performance

Performance characteristics of the BD Directigen EZ Flu A+B test were determined by calculating sensitivity and specificity for this assay compared to cell culture. The overall sensitivity and specificity of the BD Directigen EZ Flu A+B test compared to culture for all the prospectively collected nasopharyngeal wash/aspirate and throat specimens in both flu seasons combined for influenza A was 83.2% and 94.3%, respectively. For influenza B, the overall sensitivity and specificity was 75.4% and 99.3%, respectively.

Overall performance of the BD Directigen™ EZ Flu A+B test is substantially equivalent[1] to viral cell culture and DFA tests that were in use prior to May 28, 1976 and to the BD Directigen™ Flu A+B and Remel Xpect™ FLU A/B tests.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 7 - 2005

Ms. Michelle B. Bandy
Regulatory Affairs Specialist
BD Diagnostics Systems
Becton Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: k042472
Trade/Device Name: BD Directigen™ EZ-Flu A+B Kit
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: Class I
Product Code: GNX
Dated: May 31, 2005
Received: June 1, 2005

Dear Ms. Bandy:

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,

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

510(k) Number: K042472

Device Name: BD Directigen™ EZ Flu A+B

Indications for Use:

The BD Directigen™ EZ Flu A+B test is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal washes/aspirates and throat swabs of symptomatic patients. The BD Directigen EZ Flu A+B test is a differentiated test, and therefore influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. All negative test results should be confirmed by cell culture.

Prescription Use √ AND/OR Over-the-Counter Use _____
(Part 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 Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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