K101514

510(K) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
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JUL - 9 2010

CONTACT NAME: Gregory P. Payne, RAC, Director
Regulatory Affairs

DATE PREPARED: May 28, 2010

DEVICE TRADE NAME: BD Directigen™ EZ RSV assay

DEVICE COMMON NAME: Respiratory Syncytial virus serological reagents

DEVICE CLASSIFICATION: 21 CFR 866.3480

PREDICATE DEVICES : BD Directigen™ EZ RSV assay (K022133)

INTENDED USE :

The Directigen™ EZ RSV test is a rapid chromatographic immunoassay for the direct and qualitative detection of Respiratory Syncytial Virus (RSV) antigen in nasopharyngeal washes, nasopharyngeal aspirates, nasopharyngeal swabs and nasopharyngeal swab/washes from patients suspected of having a viral respiratory infection. This test is intended for in vitro diagnostic use to aid in the diagnosis of Respiratory Syncytial Virus (RSV) infections in neonatal and pediatric patients under the age of 20. It is recommended that negative test results be confirmed by cell culture.

DEVICE DESCRIPTION :

The Directigen EZ RSV antigen detection test is a chromatographic assay to detect RSV antigens extracted from various specimens of symptomatic patients. The speed and workflow of the Directigen EZ RSV test make it applicable as a "STAT" RSV antigen detection test, providing rapid, relevant information to assist with antiviral intervention and other clinical or support decisions.

DEVICE COMPARISON:

The modified kit differs from the currently marketed BD Directigen™ EZ RSV kit in the following way:

The controls have been changed from liquid to dry swabs.

SUBSTANTIAL EQUIVALENCE:

The modified device BD Directigen™ EZ RSV is substantially equivalent to the current legally marketed device, BD Directigen™ EZ RSV assay.

Modifications are as follows:

Modification	**Potential Impact of Modification**
Change of control from Liquid to dry swab.	Dry controls are more stable than liquid controls. Use of dry control swabs allows for optimal inventory management during viral outbreaks Additionally, rare customer complaints regarding control failures have been attributed to improper processing (protocol not followed, processing agent not added to liquid control). This possibility is eliminated by conversion to dry swab controls. Dry swabs controls are also supplied by most competitors. Dry swabs may not perform like liquid controls or be as stable. Stabililty and swab performance studies will define stability and performance characteristics of the swabs.

Included in the Special 510(k) are the Hazard Analysis and the associated validations and verifications conducted to address individual hazards/risks identified for this modification. The Hazard Analysis did not identify any changes that raised new issues of safety and effectiveness. The parameters listed below were evaluated in studies performed according to appropriate Design Control procedures. The modified BD Directigen™ EZ RSV assay met all current product claims for performance.

Parameter	**Result**
Dry swabs controls must be comparable in stability to current liquid controls	Data to date from accelerated stability studies have indicated 30 months at 2-30*C. Confirmatory real time stabilities have indicated 5 months at 2-30*C. Real time stabilities will continue.
Dry swabs controls must perform in the assay comparable to the current liquid controls	Dry swabs perform comparably in the assay to the current liquid controls.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Becton, Dickinson and Company
BD Diagnostics
Gregory P. Payne
Director, Regulatory Affairs and Quality Systems
11085 North Torrey Pines Road, Suite 210
La Jolla, CA 92037

JUL 0 9 2010

Re: k101514
Trade/Device Name: BD Directigen™ EZ RSV Assay
Regulation Number: 21 CFR 866.3480
Regulation Name: Respiratory syncytial virus serological reagents
Regulatory Class: Class I
Product Code: GQG
Dated: May 28, 2010
Received: June 2, 2010

Dear Mr. Payne:

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.
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 class II (Special Controls), 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.

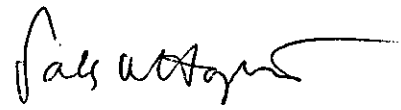
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, Ph.D.
Director, Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

510(K) Number (if known) k 101514

Device Name: BD Directigen™ EZ RSV assay

Indication for Use:

The Directigen™ EZ RSV test is a rapid chromatographic immunoassay for the direct and qualitative detection of Respiratory Syncytial Virus (RSV) antigen in nasopharyngeal washes, nasopharyngeal aspirates, nasopharyngeal swabs and nasopharyngeal swab/washes from patients suspected of having a viral respiratory infection. This test is intended for in vitro diagnostic use to aid in the diagnosis of Respiratory Syncytial Virus (RSV) infections in neonatal and pediatric patients under the age of 20. It is recommended that negative test results be confirmed by cell culture.

Prescription Use__X__ And/or Over the Counter Use____
21 CFR 801 Subpart D) (21 CFR 801Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Ute Schaf

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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