K121655

510(k) Summary of Safety and Effectiveness

MAR 2 0 2013

Submitted By: Avital Merl
Staff Regulatory Affairs Specialist
BD Medical - Medical Surgical Systems
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Franklin Lakes, NJ 07417
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Date Prepared: March 19, 2013

Device Name:

Trade Name:	BD Alcohol Swab
Common Name:	Alcohol Swab
Classification:	Unclassified
Product Code:	80 LKB

Legally marketed predicate devices to which substantial equivalence is being claimed:
K112791- Bard Access Systems'Site-Scrub IPA
K111992- Ivera Medical Corporation's Curos™ Port Protector
K083508- Excelsior Medical Corporation's SwabCap

Device Description:
The BD Alcohol Swab is a single use, sterile device that is saturated with 70% USP grade Isopropyl alcohol and intended to for needleless access site disinfection.

Intended Use:
The BD Alcohol Swab is a single use, sterile device containing 70% Isopropyl alcohol. When used for scrubbing for 5 seconds and allowing drying for 5 seconds, the BD Alcohol Swab will disinfect needless access sites prior to use. It may be used in the home or healthcare facility.

Comparison with Predicate Devices:
The BD Alcohol Swab has a similar intended use as its predicate device for disinfecting needless access sites within the home or healthcare facility. It is provided sterile and is constructed with the same 70% isopropyl alcohol antimicrobial agent as its predicated devices. It varies in technological characteristics as compared to the predicate devices as the subject device is an alcohol pad and the predicate device contains an alcohol pad-like sponge within a rigid cap design.

Testing:
BD has performed non-clinical performance testing to demonstrate its pre-defined acceptance criteria of a 4-$\log_{10}$ bacteria reduction for medical device disinfecting. These results were based upon the selection of gram positive and gram negative bacteria. The efficacy testing was performed using the following 6 bacterium on various connectors: Staphylococcus epidermidis, Staphylococcus aureus, Pseudomonas aeruginosa, Kiebsiella pneumoniae, Candida albicans, & Enterococcus faecalis. This testing demonstrated that the BD Alcohol

Swab met its requirements for its intended use and is as safe and effective as its predicate devices.

Conclusion:
The analysis and testing performed demonstrate that the BD Alcohol Swab device is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

Ms. Avital Merl
Staff Regulatory Affairs Specialist
Becton Dickinson & Company
1 Becton Drive
Franklin Lakes, New Jersey 07417-1885

Re: K121655
Trade/Device Name: BD Alcohol Swab
Regulation Number: Unclassified
Regulation Name: Pad, alcohol, device disinfectant
Regulatory Class: Unclassified
Product Code: LKB
Dated: February 25, 2013
Received: February 26, 2013

Dear Ms. Merl:

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 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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	K121655
Device Name:	BD Alcohol Swab
Indications for Use:	BD Alcohol Swab is a single use, sterile device containing 70% Isopropyl alcohol. When used for scrubbing for 5 seconds and allowing drying for 5 seconds, the BD Alcohol Swab disinfects needleless access sites prior to use. It may be used in the home or healthcare facility.

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 CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121655