



Food and Drug Administration
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January 27, 2016

Avery Dennison Belgie, BVBA
Ms. Lisa Bartakovics
Director of Global Regulatory Affairs
Tieblokkenlaan 1
Turnhout, Belgium B-2300

Re: K152923

Trade/Device Name: BD Chlorashield IV Dressing With CHG Antimicrobial
Regulation Number: Unclassified
Regulation Name: FRO
Dated: September 29, 2015
Received: October 5, 2015

Dear Ms. Bartakovics:

This letter corrects our substantially equivalent letter of November 5, 2015.

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 contact the Division of Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152923

Device Name

BD ChloroShield IV Dressing with CHG antimicrobial

Indications for Use (Describe)

The BD ChloroShield IV Dressing with CHG antimicrobial, per K152923, is intended to cover and protect catheter sites and to secure devices to the skin. Common applications include securing and covering IV catheters, other intravascular catheters and percutaneous devices.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) Summary
K152923

Avery Dennison Belgie, BVBA
BD ChloroShield IV Dressing with CHG antimicrobial

1. Submitter Information

Name: Avery Dennison Belgie, BVBA
Address: Tieblokkenlaan 1
Turnhout, Belgium B-2300
Telephone Number: 1-312-629-4608

Contact Person: Lisa Bartakovics
Telephone Number: 1-312-629-4608
Email: Lisa.Bartakovics@averydennison.com

Date Prepared: September 29, 2015

2. Device Name

Trade Name: BD ChloroShield IV Dressing with CHG antimicrobial
Common Name: Dressing, Wound, Drug
Classification Name: Unclassified

3. Predicate Device(s)

- K113836, Benehold CHG Transparent Film Dressing

4. Device Description

The BD ChloroShield IV Dressing with CHG antimicrobial consists of a transparent adhesive dressing with integrated Chlorhexidine Gluconate (CHG), a well known antiseptic agent with broad-spectrum antimicrobial activity, which serves as a preservative within the dressing.

5. Indications for Use

The BD ChloroShield IV Dressing with CHG Antimicrobial, per K152923, is intended to cover and protect catheter sites and to secure devices to the skin. Common applications include securing and covering IV catheters, other intravascular catheters and percutaneous devices.

The Indications for Use have not been altered and are the same as those listed within the original 510(k) application (K113836).

Avery Dennison Belgie BVBA- CONFIDENTIAL
Special 510(k) Submission: BD ChloroShield IV Dressing with CHG antimicrobial

6. Technological Characteristics and Substantial Equivalence

Avery Dennison submitted a 510k application for an IV Dressing containing Chlorhexidine Gluconate (CHG) within submission K113836. The 510k submission was cleared in 2012 under the principle that the CHG was considered a preservative within the device and thus met the requirements for “preservative effectiveness”. The CHG specification within K113836 demonstrated antimicrobial efficacy testing well above those required.

Upon further review, it was determined that the CHG specification for the Avery Dennison IV Dressing could be expanded and still meet the requirements stated within submission K113836. Therefore, this Special 510k application was authored to expand the specification for CHG content.

Although the specification of the Chlorhexidine Gluconate has been modified, the fundamental technology of the finished device has not been altered. The inclusion of CHG as a preservative within the adhesive of the dressing, which is the fundamental scientific technology, is unaffected by the change to the specification since antimicrobial efficacy testing continues to meet the stated requirements. In addition, the performance, functionality and manufacturing methods remain unchanged.

7. Performance Testing

Submission K113836 contained antimicrobial efficacy testing to the requirements set forth within USP 51. Therefore, any change to the specification of the CHG contained within the BD ChlorShield device must meet the requirements as stated within K113836. The modification of the specification was subjected to design controls. The resulting verification/ validation activities confirmed that the specification change was well within the requirements. Antimicrobial efficacy test results demonstrated conformance thus validating the acceptability of the proposed specification change.

8. Conclusion

Testing demonstrates that the change to the specification for CHG content does not affect the technological characteristics of the device nor the intended use as listed within the original submission (K113836). Conformance to the requirements set forth within the original submission was confirmed through antimicrobial efficacy testing. Therefore the proposed change to the specification of the finished device is acceptable and equivalent to the design set forth within the original submission.