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

July 17, 2017

Avery Dennison Belgie BVBA
Lisa Bartakovics
Senior Director of Global Regulatory Affairs
Tieblokkenlaan 1
Turnhout, B-2300 BE

Re: K170407
Trade/Device Name: BD Chlorashield IV Dressing With CHG Antimicrobial
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 13, 2017
Received: June 15, 2017

Dear Lisa Bartakovics:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170407

Device Name
BD ChloraShield IV Dressing with CHG antimicrobial

Indications for Use *(Describe)*
The BD ChloraShield IV Dressing with CHG antimicrobial 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - K170407

Avery Dennison België BVBA
BD ChloraShield™ IV Dressing with CHG antimicrobial

1. Submitter Information

Name:	Avery Dennison België 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: February 07, 2017

2. Device Name

Trade Name:	BD ChloraShield™ IV Dressing with CHG antimicrobial
Common Name:	Dressing, Wound, Drug
Classification Name:	Unclassified
Product Code:	FRO

3. Predicate Device(s)

K113836, Benehold™ CHG Transparent Film Dressing

4. Device Description

The BD ChloraShield™ IV Dressing with CHG antimicrobial consists of a transparent adhesive dressing integrated with 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 ChloraShield™ IV Dressing with CHG Antimicrobial 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 are the same as those listed within the predicate 510(k) application (K113836).

6. Technological Characteristics and Substantial Equivalence

Avery Dennison submitted a 510k application for an IV Dressing containing Chlorhexidine Gluconate (CHG) within submission K113836. The device cleared within K113836 was sterilized through gamma radiation.

Following a series of Engineering trials, it was determined that the BD ChloraShield™ IV Dressing with CHG antimicrobial could also be sterilized by Ethylene Oxide gas. Thus, a project was undertaken to demonstrate that the dressing manufactured by Avery Dennison was compatible with Ethylene Oxide sterilization. Therefore, the purpose of this Traditional 510(k) submission is to obtain clearance for the Ethylene Oxide sterilization of the BD ChloraShield™ IV Dressing with CHG antimicrobial.

Although the method of sterilization for the ChloraShield™ IV dressing has been modified, the Sterility Assurance Level (SAL) of the device remains 10^{-6}. The inclusion of CHG within the dressing, which is the fundamental scientific technology, is unaffected by the change in sterilization method. In addition, the performance, functionality and manufacturing methods remain unchanged.

7. Performance Testing

Performance testing for the BD ChloraShield™ IV Dressing with CHG antimicrobial utilized the same test methodology as the predicate device within K113836. Since the CHG concentration, materials and method of manufacture remain unchanged per the predicate device, this Traditional 510(k) submission mirrors the requirements set forth in K113836. The compilation of laboratory and performance testing demonstrates that the BD ChloraShield™ IV Dressing with CHG antimicrobial is substantially equivalent to the predicate device in K113836. The resulting verification/ validation activities confirmed that the use of Ethylene Oxide sterilization met sterility requirements of 10^{-6} without compromising the performance of the device.

8. Conclusion

Testing demonstrates that the change in sterilization method for the BD ChloraShield™ IV Dressing with CHG antimicrobial does not affect the required Sterility Assurance Level, technological characteristics, performance or the intended use as listed within the predicate submission (K113836). Furthermore, substantial equivalence to the predicate device was confirmed through sterility results, stability or shelf-life (including antimicrobial efficacy testing) and bench testing. Therefore, the change to the sterilization method of the finished device is acceptable and substantially equivalent to the design set forth within the predicate submission.