Special 510(k) Summary
Avery Dennison Belgie, b.v.b.a.
ChloraShield IV Dressing with CHG antimicrobial

1. **Submitter Information**

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Date Prepared:	December 10, 2013

2. **Device Name**

Trade Name:	ChloraShield 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 ChloraShield 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 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 have not been altered and are the same as those listed within the original 510(k) application (K113836).

6. **Technological Characteristics and Substantial Equivalence**

The change in the packaging material does not affect the substantial equivalence of the device per submission K113836. Although the packaging 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 packaging. In addition, the performance, functionality and manufacturing methods remain unchanged.

7. **Performance Testing**

Sterility testing was conducted to verify the change to the packaging material did not negatively impact the sterility assurance level. The sterility assurance level within the original 510(k) submission was 10^{-6} and testing confirmed that the revised packaging achieved a sterility assurance level of 10^{-6} thus there was no impact to the sterility. In addition to the sterility testing, the seal strength was verified. In summary, the following performance tests were performed as part of verification/validation activities:

- Seal Strength
- Bubble Leak Test
- Sterility

8. **Conclusion**

Testing demonstrates that the change in the packaging material does not affect the technological characteristics of the device or the intended use as listed within the original submission (K113836). The method of sterilization, gamma, remains unchanged. Furthermore, there has been no decrease in the sterility assurance level of the ChloraShield IV Dressing with CHG antimicrobial thus the proposed change in the packaging of the device is equivalent to that of the original submission.

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 13, 2014

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

Re: K133764
Trade/Device Name: ChloraShield IV Dressing with CHG Antimicrobial
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 10, 2014
Received: February 12, 2014

Dear Ms. 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 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. 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,

David Krause-S

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

Enclosure

Indications for Use

510(k) Number (if known): K133764

Device Name: ChloraShield IV Dressing with CHG Antimicrobial

Indications for Use:

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Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number