August 18, 2023

Smith & Nephew Medical Limited
Hannah Sharp
Senior Regulatory Affairs Specialist
101 Hessle Road
Hull, Yorkshire HU3 2BN
United Kingdom

Re: K223526
Trade/Device Name: ALLEVYN Ag+ Border Antimicrobial Silicone Gel Adhesive Composite Hydrocellular Foam Dressing, ALLEVYN Ag+ Border Sacrum Antimicrobial Silicone Gel Adhesive Composite Hydrocellular Foam Dressing, ALLEVYN Ag+ Surgical Antimicrobial Silicone Gel Adhesive Composite Hydrocellular Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 22, 2022
Received: July 21, 2023

Dear Hannah Sharp:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223526

Device Name
ALLEVYN Ag+ dressing

Indications for Use *(Describe)*
ALLEVYN Ag+ dressing is indicated for the management of exuding wounds such as leg and foot ulcers, pressure ulcers, traumatic and surgical wounds, superficial and partial thickness burns.

ALLEVYN Ag+ dressing can also be used under compression bandaging.

Silver sulfate present in the dressing helps reduce microbial colonization on the dressing.

ALLEVYN Ag+ dressing should be used under the supervision of a qualified healthcare professional.

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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510(k) Summary: K223526

21 CFR 807.92 (a)(1): Submitter's Information	
510(k) Owner Name	Smith & Nephew Medical Ltd
Address	101 Hessle Road, Hull, HU3 2BN, United Kingdom
Establishment Registration Number	8043484
Contact Name	Hannah Sharp, Senior Regulatory Affairs Specialist
Telephone Number	(+44)7740 531714
Date Prepared	August 17, 2023
21 CFR 807.92 (a)(2): Device Information	
Device Name (Trade/Proprietary Name)	ALLEVYN™ Ag+ dressing Variants: • ALLEVYN™ Ag+ Border (including Sacrum) • ALLEVYN™ Ag+ Surgical
Common Name	Antimicrobial silicone gel adhesive composite hydrocellular foam dressing
Review Panel	General and Plastic Surgery
Regulation Number	N/A (Unclassified)
Regulatory Class	Unclassified (Pre-amendment)
Product Code	FRO
21 CFR 807.92 (a)(3): Legally marketed device to which equivalence is claimed	**510(k) Number:** K100029 **Device Name:** MEPILEX™ Border Ag Dressing

21 CFR 807.92 (a)(4): Device Description

The ALLEVYN Ag+ dressing is a; sterile, single-use, composite, absorbent, antimicrobial wound dressing containing silver sulfate within an absorbent pad.

The primary function of the ALLEVYN Ag+ dressing is to absorb exudate and provide a moist wound-healing environment that is optimal for low to highly exuding wounds. As a secondary function the silver in the polyurethane absorbent foam layer of the ALLEVYN Ag+ dressing helps to reduce or inhibit microbial colonization of the device based on in-vitro testing. The antimicrobial agent (silver), is derived from silver sulfate added to the subject device (ALLEVYN Ag+ dressing).

The ALLEVYN Ag+ dressing range includes the following variants which all have the same intended use / indications for use and technological characteristics, and which differ in dimensions, shape and top film colour only):

- **ALLEVYN Ag+ Border (including Sacrum)**
  Dressings available in square and sacrum sizes with a printed ('Ag+') pink transparent top film.
- **ALLEVYN Ag+ Surgical**
  Dressings available in rectangles with a printed ('Ag+') clear transparent top film.

The ALLEVYN Ag+ dressing is a composite antimicrobial dressing consisting of:

- **Top Film**: Breathable transparent polyurethane top film (clear or with pink depending on dressing size), printed with 'Ag+'

- **Superabsorbent Pad**: Non-woven superabsorbent particulate pad with cut pattern of slits for flexibility and conformability

- **Absorbent polyurethane foam layer containing silver sulfate:** Absorbent polyurethane foam pad impregnated with a powder mix including silver sulfate
- **Wound Contact Layer (WCL)**: A perforated WCL made of polyurethane film coated with silicone gel adhesive on wound facing side
- **Release Handles**: Plain and perforated transparent films

The ALLEVYN Ag+ dressing is provided individually packed in a sealed pouches made from grid-lacquer paper and polyester film laminate; the sealed pouch forms the sterile barrier for each dressing. Multiple pouched dressings are provided in a carton along with a user manual.
The ALLEVYN Ag+ dressing is provided terminally sterilized via Ethylene Oxide Sterilization to a 10^{-6} sterility assurance level.

21 CFR 807.92 (a)(5): Intended Use / Indications for Use

ALLEVYN Ag+ dressing is indicated for the management of exuding wounds such as leg and foot ulcers, pressure ulcers, traumatic and surgical wounds, superficial and partial thickness burns.

ALLEVYN Ag+ dressing can also be used under compression bandaging.

Silver sulfate present in the dressing helps reduce microbial colonization on the dressing.

ALLEVYN Ag+ dressing should be used under the supervision of a qualified healthcare professional.

21 CFR 807.92 (a)(6): Comparison of Technological Characteristics between the Subject and Predicate Devices

The ALLEVYN Ag+ dressing is substantially equivalent to predicate MEPILEX™ BORDER AG DRESSING (K100029) based on:

- The same intended use / indications for use, same principles of operation and similar technological characteristics
- Any minor differences in technological characteristics, do not raise new or different questions of safety and effectiveness when compared to the predicate device, as demonstrated via performance verification testing.

In-vitro bench testing and animal studies are therefore sufficient to assure the subject device is as safe and effective as the predicate device.

The following table shows a comparison of the technological characteristics between the subject device and predicate device.

Product Characteristic	**Subject Device (ALLEVYN Ag+ Dressing)**	**Predicate Device (MEPILEX™ Border Ag Dressing)**
Product Code	FRO (Dressing, Wound, Drug)	FRO (Dressing, Wound, Drug)
Product Classification	Unclassified (Pre-amendment) Combination Product (device-drug)	Unclassified (Pre-amendment) Combination Product (device-drug)
Intended Use / Indications for Use	The management of exuding wounds such as leg and foot ulcers, pressure ulcers, traumatic and surgical wounds, superficial and partial thickness burns Can also be used under compression bandaging Silver sulfate present in the dressing helps reduce microbial colonization on the dressing ALLEVYN Ag+ dressing should be used under the supervision of a qualified healthcare professional	The management of exuding wounds such as leg and foot ulcers, pressure ulcers, traumatic and surgical wounds, superficial and partial thickness burns Can also be used under compression bandaging Silver sulfate present in the dressing helps reduce microbial colonization on the dressing
User Group	Rx Only. Should be used under the supervision of a qualified healthcare professional	Rx Only. Should be used under the supervision of a qualified healthcare professional
Dressing Wear Time	Up to 7 days, except in the sacral area where dressings can be left in place for up to 5 days	Up to 7 days
Anatomical sites	Any (including Sacrum)	Any (including Sacrum)

Materials	• **Top Film**: Breathable transparent polyurethane top film (clear or with pink pigment), printed with 'Ag+' • **Superabsorbent Pad**: Non-woven Superabsorbent Particulate (SAP) fibrous layer • **Absorbent polyurethane foam layer containing silver sulfate**, and other excipients including activated charcoal • **Wound Contact Layer (WCL):** Perforated film wound contact layer, coated with a silicone gel adhesive on the wound facing side • **Release Handles:** Removable protective material	• **Top Film**: Breathable transparent polyurethane top film clear or with beige pigment) • Non-woven wicking layer • **Superabsorbent Pad**: Non-woven superabsorbent fibrous layer (polyacrylate fibres) • Non-woven wicking layer • Wicking PE/PP non-woven • **Absorbent polyurethane foam layer containing silver sulfate** and activated charcoal throughout • **Wound Contact Layer (WCL):** Safetac™ soft silicone wound contact layer • **Release Handles:** Removable protective material
Function	Fluid absorbency	Fluid absorbency
Function	Fluid retention in the dressing	Fluid retention in the dressing
Function	Breathability/evaporation of fluid	Breathability/evaporation of fluid
Function	Extensibility and conformability	Extensibility and conformability
Function	Bacterial barrier	Bacterial barrier
Function	Antimicrobial effect in the dressing	Antimicrobial effect in the dressing
Antimicrobial Agent - Identity	Silver, derived from silver sulfate	Silver, derived from silver sulfate
Antimicrobial Agent - Concentration	1.9 – 3.0 mg/cm^2	1.2 mg/cm^2 (Information on range of concentration of silver sulfate not publicly available)
Antimicrobial Agent – Mechanism of Release	Silver, derived from silver sulfate. Dissolution by contact with aqueous solution (e.g., wound exudate)	Silver, derived from silver sulfate. Dissolution by contact with aqueous solution (e.g., wound exudate)
Method of Sterilization	Ethylene Oxide	Ethylene Oxide

Dressing Sizes	**ALLEVYN Ag+ Border** dressing (with pink outer film): • 7.5cm x 7.5cm (3” x 3”) --- • 17.5cm x 17.5cm (7” x 7”) **ALLEVYN Ag+ Border Sacrum** dressing (with pink outer film): • 17.2cm x 17.5cm (6.8” x 6.9”) & • 21.6cm x 23cm (8.5” x 9”) **ALLEVYN Ag+ Surgical** dressing (with clear outer film): • 10cm x 20cm (4” x 8”) --- • 10cm x 30cm (4” x 11.8”)	**MEPILEX Border Ag** dressings (with beige outer film): • 7.5cm x 7.5cm (3” x 3”) --- • 10cm x 30cm (4” x 12”) **MEPILEX Border Sacrum Ag** dressings (with beige outer film): • 18cm x 18cm (7.2” x 7.2”) & • 23cm x 23cm (9.2” x 9.2”) **MEPILEX Border Post-Op Ag** dressings (with clear outer film): • 10cm x 15cm (4” x 6”) --- • 10cm x 35cm (4” x 14”)

21 CFR 807.92 (b)(1): Brief discussion of nonclinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence

Non-clinical performance testing for the subject device was conducted according to applicable sections of voluntary standards in order to document the following properties and to support substantial equivalence of the subject device:

Performance Bench Testing
Device claims have been based off the below in-vitro testing.

Physical Testing Including:

- Wound Model, Absorbency, Moisture Vapor Transmission Rate, Adhesion, Adhesiveness, Conformability (Extensibility), Waterproofness and Bacterial Barrier Performance.

Antimicrobial Effectiveness Testing in compliance with:

- Modified AATCC TM100-2019: Test Method for Antibacterial Finishes on Textile Materials

Biocompatibility Assessment and Testing in compliance with:

- ISO 10993: The Biological Evaluation of Medical Devices Standard, with particular reference to Part 1 (2018): Evaluation and testing within a risk management process
- CDRH Guidance: "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part1: Evaluation and testing within a risk management process" issued September 4, 2020.

Human Factors and Usability Testing in compliance with:

- CDRH Guidance: Applying Human Factors and Usability Engineering to Medical devices and ISO 62366 - 1:2015 and IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION.

Conclusion
Based on the results of the performance testing undertaken, it can be concluded that the subject device (ALLEVYN Ag+ dressing) is as safe and effective as the predicate device. The subject device is substantially equivalent to MEPILEX™ BORDER AG DRESSING (K100029).

21 CFR 807.92 (b)(2): Brief discussion of clinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence

No clinical data is relied upon in this submission to determine substantial equivalence.

21 CFR 807.92 (b)(3): Conclusions drawn

Based on the comparison and analysis provided within this submission, the subject device can be deemed substantially equivalent to the legally marketed predicate device (MEPILEX™ Border Ag Dressing). To the extent that there are differences between the subject device and the predicate, these differences do not raise new or different questions of safety or effectiveness when compared to the predicate device.