December 17, 2024

Smith & Nephew Medical Limited
Andrew Daglish
Regulatory Affairs Manager
101 Hessle Road
Hull, East Riding of Yorkshire HU3 2BN
United Kingdom

Re: K242146
Trade/Device Name: BIOBRANE Dressing; BIOBRANE Glove
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 22, 2024
Received: July 23, 2024

Dear Andrew Daglish:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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)*
K242146

Device Name
BIOBRANE Dressing
BIOBRANE Glove

Indications for Use *(Describe)*
BIOBRANE Dressings are indicated for:
- Covering clean partial thickness burn wounds
- Split thickness donor sites

BIOBRANE Glove is indicated for:
- Covering clean partial thickness burn wounds of the hand.

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.

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"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."

K242146 510(k) Summary

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	Andrew Daglish - Regulatory Affairs Manager
Telephone Number	07890 426317
Date Prepared	10-Dec-2024
21 CFR 807.92 (a)(2): Device Information	
Device Name (Trade/Proprietary Name)	BIOBRANE Dressing BIOBRANE Glove
Common Name	Wound Dressing With Animal-Derived Material(S)
Review Panel	General and Plastic Surgery
Regulation Number	N/A (Unclassified)
Regulatory Class	Unclassified (Pre-amendment)
Product Code	KGN
21 CFR 807.92 (a)(3): Legally marketed device to which equivalence is claimed	**510(k) Number:** K901369 **Device Name:** GREEN LABEL BIOBRANE II AND RED LABEL BIOBRANE II
21 CFR 807.92 (a)(4): Device Description	
BIOBRANE Dressing and BIOBRANE Glove are wound dressings made from an ultrathin, semi-permeable, perforated silicone membrane that is mechanically bonded to a flexible knitted tri-filament nylon fabric. Denatured porcine dermal collagen is bonded to the silicone–nylon membrane to provide a flexible and conformable dressing with adherence properties and a hydrophilic surface.	
21 CFR 807.92 (a)(5): Intended Use / Indications for Use	
BIOBRANE Dressings are indicated for: • Covering clean partial thickness burn wounds • Split thickness donor sites BIOBRANE Glove is indicated for: • Covering clean partial thickness burn wounds of the hand.	

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

Product Characteristic	Subject Device (BIOBRANE, K242146)	Predicate Device (BIOBRANE II, K901369)	Substantial Equivalence Decision
Intended Use	Wound Management	Wound Management	Same
Indications for Use	BIOBRANE Dressing is indicated for: • Covering clean partial thickness burn wounds • Split thickness donor sites BIOBRANE Glove is indicated for: • Covering clean partial thickness burn wounds of the hand.	RED LABEL BIOBRANE II is indicated for: • Clean partial thickness burn wounds • Donor sites GREEN LABEL BIOBRANE II is indicated for: • Clean partial thickness burn wounds • Donor sites	BIOBRANE Dressings specify split thickness donor sites and BIOBRANE Gloves specify hand sites. The indications for use of the subject device are more precise within the scope of the predicate device's indications for use and the indications for use of the subject device are substantially equivalent to the predicate device.
Principles of operation	Excess fluid can drain from the perforations.	Excess fluid can drain from the perforations.	Same

Materials and Structure	Silicone membrane, nylon, and collagen Porous silicone and nylon knit bi-layer sheet with collagen coating	Silicone membrane, nylon, and collagen Porous silicone and nylon knit bi-layer sheet with collagen coating	Same
Silicone Membrane Function	A thin transparent, perforated, polymeric film. Creates a film structure over the top of the nylon to encase the dressing, creating a moist wound-healing environment.	A thin transparent, perforated, polymeric film. Creates a film structure over the top of the nylon to encase the dressing, creating a moist wound-healing environment.	Same
Nylon Function	A weave of polymeric tri-filament yarn, partially embedded into the silicone membrane.	A weave of polymeric tri-filament yarn, partially embedded into the silicone membrane.	Same
Collagen Function	Denatured porcine dermal collagen coated to the silicone-nylon dressing. The collagen component adheres to the fibrin on a clean wound surface and adheres the dressing to the wound.	Denatured porcine dermal collagen coated to the silicone-nylon dressing. The collagen component adheres to the fibrin on a clean wound surface and adheres the dressing to the wound.	Same
Principal Operator	Trained healthcare professional (HCP) only	Trained healthcare professional (HCP) only	Same

Environment of Use	Healthcare facility and home use (inpatient and outpatient)	Healthcare facility and home use (inpatient and outpatient)	Same
Single-Use or Reusable	Single-Use	Single-Use	Same
Sterilization	Moist heat	Moist heat	Same
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Same
Shelf Life	3 years	3 years	Same
Biocompatibility	The device complies with ISO 10993	The device complies with ISO 10993	Same

Device Dimensions	• Dressing 13cm x 13cm / 5in x 5in • Dressing 13cm x 38cm / 5in x 15in • Dressing 25cm x 38cm / 10in x 15in • Dressing 38cm x 50cm / 15in x 20in • Glove Paediatric • Glove Small • Glove Medium • Glove Large	• RED LABEL 13cm x 13xm / 5in x 5in • RED LABEL 13cm x 38cm / 5in x 15in • RED LABEL 25cm x 38cm / 10in x 15in • RED LABEL 38cm x 50cm / 15in x 20in • GREEN LABEL Paediatric • GREEN LABEL Small • GREEN LABEL Medium • GREEN LABEL Large	Same
Anatomical sites	BIOBRANE Dressing: All body areas BIOBRANE Glove: Hand	RED LABEL BIOBRANE II: All body areas GREEN LABEL BIOBRANE II: Hand	Same

21 CFR 807.92 (b)(1): Brief discussion of nonclinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence
A series of bench performance verification tests and product characterization have been completed to confirm the subject device meets design specifications in support of the performance of BIOBRANE, in addition to demonstrating substantial equivalence to the predicate device of the BIOBRANE II (K901369).
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
In establishing substantial equivalence to the predicate device, Smith & Nephew Medical Ltd evaluated the indications for use, principle of operation, materials, technology, product specifications and biocompatibility requirements of the device. Performance testing has been completed to demonstrate that BIOBRANE is substantially equivalent to the predicate device for the intended use.