June 24, 2026

Aroa Biosurgery , Ltd.
Thanh Minh Lam
Regulatory Specialist
2 Kingsford Smith Pl.
Airport Oaks
Auckland, 2022
New Zealand

Re: K260669
Trade/Device Name: Endoform Dermal Template
Regulatory Class: Unclassified
Product Code: KGN
Dated: March 15, 2026
Received: March 16, 2026

Dear Thanh Minh Lam:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 PhD,
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)*
K260669

Device Name
Endoform Dermal Template

Indications for Use *(Describe)*
Endoform Dermal Template is supplied sterile and is intended for single use in the management of the following wounds:

* Partial and full thickness wounds
* Pressure ulcers
* Venous ulcers
* Diabetic ulcers
* Chronic vascular ulcers
* Tunneled/undermined wounds
* Surgical wounds (donor sites, grafts, post Moh's surgery, post laser surgery, podiatric, wound dehiscence)
* Traumatic wounds (abrasions, lacerations, partial-thickness burns, and skin tears)
* Draining wounds

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.

510(k) SUMMARY
(as required by 21 CFR 807.92)

I. Submitter

Name:	Aroa Biosurgery Ltd.
Address:	2 Kingsford Smith Place, Airport Oaks, Auckland 2022, New Zealand
Phone:	+64 210 417 216
Contact Person:	Mr. Thanh Minh Lam
Email:	minh.lam@aroa.com
Date Prepared:	24 June 2026

II. Device

Trade or Proprietary Name:	Endoform Dermal Template
Common or Usual Name:	Endoform Dermal Template
Classification Name:	Unclassified
Product Code:	KGN
Device Classification:	Unclassified

III. Predicate Device

Product Name	510(k) Number	Applicant
Endoform Dermal Template	K092096	Aroa Biosurgery Ltd.

IV. Device Description

Endoform Dermal Template is a 100% w/w intact extracellular matrix (ECM), manufactured from ovine (sheep) forestomach tissue. When rehydrated with wound exudate or sterile saline, Endoform Dermal Template transforms into a soft, conforming sheet, which is incorporated into the wound over time.

V. Indications for Use

Endoform Dermal Template is supplied sterile and is intended for single use in the management of the following wounds:

- Partial and full thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (donor sites, grafts, post Moh's surgery, post laser surgery, podiatric, wound dehiscence)

- Trauma wounds (abrasions, lacerations, partial-thickness burns, and skin tears)
- Draining wounds

VI. Comparison of Technological Characteristics

The indications for use statements for the subject and predicate devices are similar. The subject Endoform Dermal Template has the same technological characteristics as the predicate device (K092096). A comparison of the subject and predicate devices is provided below.

Design Characteristic	**Subject Device Endoform Dermal Template Sizes up to 1000 cm²**	**Predicate Device Endoform Dermal Template Sizes up to 400 cm²**	**Comparison of Subject and Predicate Devices**
Intended Use	Endoform® Dermal Template is supplied sterile and is intended for single use in the management of the following wounds: Partial and full thickness wounds; Pressure ulcers; Venous ulcers; Diabetic ulcers; Chronic vascular ulcers; Tunneled/undermined wounds; Surgical wounds (donor sites, grafts, post Moh's surgery, post laser surgery, podiatric, wound dehiscence); Trauma wounds (abrasions, lacerations, partial-thickness burns, and skin tears); Draining wounds	Endoform® Dermal Template is supplied sterile and is intended for single use in the treatment of the following wounds: Partial and full-thickness wounds; Pressure ulcers; Venous ulcers; Diabetic ulcers; Chronic vascular ulcers; Tunnelled/undermined wounds; Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence); Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears); Draining wounds	Equivalent

Design Characteristic	Subject Device Endoform Dermal Template Sizes up to 1000 cm²	Predicate Device Endoform Dermal Template Sizes up to 400 cm²	Comparison of Subject and Predicate Devices
Animal Origin	Ovine	Ovine	Identical
Tissue Type	Forestomach	Forestomach	Identical
Nominal Sizes	Perforated or non-perforated sheets ranging in size up to 1000 cm²	Perforated or non-perforated sheets ranging in size up to 400 cm²	Larger sizes up to 1000 cm²
Presentation	Sterile (EO), lyophilized sheets	Sterile (EO), lyophilized sheets	Identical
Plys	1-ply	1-ply	Identical
Components	Ovine derived collagen and associated ECM components: Collagen I; Collagen III	Ovine derived collagen and associated ECM components: Collagen I; Collagen III	Identical
Packaging	Devices <400 cm²: packaged in single-use, peel-open pouches that are heat sealable and gas-permeable (sterilant penetration). Devices >400 cm² - <1000 cm²: heat sealed Tyvek/film medical pouch, using a double pouch (inner and outer) configuration	Packaged in single-use, peel-open pouches that are heat sealable and gas-permeable (sterilant penetration)	Larger EDT sizes utilize heat sealed Tyvek/film medical pouches instead of peel-open pouches

Design Characteristic	Subject Device Endoform Dermal Template Sizes up to 1000 cm²	Predicate Device Endoform Dermal Template Sizes up to 400 cm²	Comparison of Subject and Predicate Devices
Sterilization	EO	EO	Identical
SAL	10^{-6}	10^{-6}	Identical
Shelf Life	36 months	36 months	Identical

The only differences between the subject device and the predicate device are:
1. The introduction of larger sizes (up to 1000 cm²) compared to the currently cleared sizes (up to 400 cm²).
2. A packaging change from a medical grade paper/film packaging system to a double pouch Tyvek/film system, validated in accordance with ISO 11607 and consistent with the packaging used for the cleared Endoform Reconstructive Template (K181935).

The increase in maximum device size does not impact on the safety and effectiveness of the device, as the technological characteristics and functionality are not dependent on size.

VII. Performance Data

Bench testing was previously conducted to support the clearance of the predicate device (K092096). The subject device utilizes the same design, materials, and manufacturing processes as the cleared predicate device, with the only modifications being an increase in device size and a packaging change to accommodate the larger sizes.

VIII. Conclusion

The subject device Endoform Dermal Template is substantially equivalent to the predicate device (K092096) with respect to indications for use, overall design and technological characteristics. The differences between the subject and predicate device do not raise new questions of safety or effectiveness of use of the subject device.