June 03, 2025

Aroa Biosurgery Ltd.
Stacy Spies
Senior Regulatory Affairs Specialist
2 Kingsford Smith Place
Airport Oaks
Auckland, 2022
New Zealand

Re: K250598
Trade/Device Name: Endoform Reconstructive Template - PLGA
Regulation Number: 21 CFR 878.3300
Regulation Name: Mesh, Surgical
Regulatory Class: Class II
Product Code: FTM, FTL
Dated: February 27, 2025
Received: February 28, 2025

Dear Stacy Spies:

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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K250598

Device Name
Endoform™ Reconstructive Template – PLGA

Indications for Use *(Describe)*
Endoform™ Reconstructive Template – PLGA is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing material to obtain the desired surgical outcome.

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.***

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# 510(k) Summary

| | |
|---|---|
| **Contact person/submitter** | Stacey Spies<br>Regulatory Affairs Manager<br>Aroa Biosurgery Ltd. |
| **Prepared on** | 14 May 2025 |
| **Contact details** | 2 Kingsford Smith Place<br>Airport Oaks, Auckland 2022, New Zealand<br>+64 9 369 3035 |
| **Trade name** | Endoform™ Reconstructive Template - PLGA |
| **Common name** | Surgical Mesh |
| **Regulation Number** | 21 CFR 878.3300 |
| **Classification name** | Mesh, Surgical |
| **Product code** | FTM |
| **Predicate device** | Endoform™ Reconstructive Template (K153633) |
| **Reference device** | OviTex PRS (Long Term Resorbable) (K214070) |

## Device Description

Endoform™ Reconstructive Template – PLGA is a surgical mesh comprised of multiple layers of ovine-derived extracellular matrix reinforced with poly(lactic-co-Glycolic) acid (PLGA). The device design includes a range of shapes, sizes, and thicknesses in surface areas up to 400cm$^2$, to give a range of strengths as required for a particular implant procedure. Devices are terminally sterilized by ethylene oxide (EO) sterilization.

## Intended Use / Indications for Use

Endoform™ Reconstructive Template – PLGA is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing material.

## Technological Comparison

The technological characteristics of both Endoform™ Reconstructive Template – PLGA and the predicate device are similar; in that they are both composed of sheets of ovine-derived extracellular matrix sewn together with a polymeric suture. The primary difference between the subject and predicate device is the type of polymer used, with the subject device utilizing poly(lactic-co-Glycolic) acid (PLGA) and the predicate device using polyglycolic acid (PGA). The subject device is offered in the same range of shapes, sizes, and thicknesses as the predicate device. Endoform™ Reconstructive Template – PLGA maintains the same fundamental technological characteristics as the predicate device with respect to material types, biocompatibility, device specifications, and sterilization.

| | **Subject Device** | **Predicate Device** |
|---|---|---|
| **Device name** | **Endoform™ Reconstructive Template - PLGA** | **Endoform™ Reconstructive Template** |
| **Manufacturer** | **Aroa Biosurgery Ltd.** | **Aroa Biosurgery Ltd.** |
| **510K Number** | K250598 | K153633 |
| **Intended use** | Endoform™ Reconstructive Template - PLGA is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. | Endoform™ Reconstructive Template is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. |
| **Indications for Use** | Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing material to obtain the desired surgical outcome. | Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome. |
| **Animal Derived Material** | Ovine-derived extracellular matrix | Ovine-derived extracellular matrix |
| **Polymeric Monofilament** | Poly(lactic-co-Glycolic) acid (PLGA) | Polyglycolic acid (PGA) |
| **Maximum Device Size** | Up to 400cm$^2$ | Up to 400cm$^2$ |
| **Packaging** | Double Tyvek 2FS and PET/PE pouch inside a cardboard zip-style envelope | Double Tyvek 2FS and PET/PE pouch inside a cardboard zip-style envelope |
| **Endotoxin Content** | <20 EU/device | <20 EU/device |

| | Subject Device | Predicate Device |
|---|---|---|
| **Device name** | **Endoform™ Reconstructive Template - PLGA** | **Endoform™ Reconstructive Template** |
| **Manufacturer** | **Aroa Biosurgery Ltd.** | **Aroa Biosurgery Ltd.** |
| **510K Number** | K250598 | K153633 |
| **Method of Sterilization and Sterility Assurance Level (SAL)** | Ethylene Oxide, $10^{-6}$ | Ethylene Oxide, $10^{-6}$ |
| **Usage** | Single Use | Single Use |
| **Use Setting** | For use in a surgical setting by or under the supervision of a medical professional. | For use in a surgical setting by or under the supervision of a medical professional. |

## Non-Clinical Performance Data

Non-clinical testing has been conducted to evaluate the safety and performance characteristics of Endoform™ Reconstructive Template - PLGA in support of the substantial equivalence determination. Results of testing confirm that the proposed device meets all product specifications and supports substantial equivalence to the predicate device.

Biocompatibility assessment and testing was performed in accordance with the FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*, as recognized by FDA. Non-clinical testing included mechanical strength, suture retention, elastic modulus, collagen differential scanning calorimetry, endotoxin, bioburden, and compliance testing. The results of all testing and the accompanying biocompatibility assessments have demonstrated that Endoform™ Reconstructive Template - PLGA devices are safe for use and will not cause any unacceptable risk to patients or users when used as intended.

## Clinical Performance Data

Substantial equivalence was not based on an assessment of clinical performance data.

## Conclusions

Endoform™ Reconstructive Template – PLGA is substantially equivalent to Endoform Reconstructive Template (K153633), which has been cleared by FDA for the same intended use. Endoform™ Reconstructive Template – PLGA has similar technological characteristics and principles of operation as the predicate device and the minor differences between the subject and predicate devices do not raise new questions of

safety and effectiveness. Results of non-clinical, mechanical, and biocompatibility testing support the conclusion that Endoform™ Reconstructive Template – PLGA is as safe and effective as the predicate device.