DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 16, 2016

Aroa Biosurgery Limited
c/o Gordon MacFarlane, Ph.D., RAC
ICON Clinical Research LLC
62 Forest Street
Marlborough, MA 01752

Re: K153632
Trade/Device Name: Endoform® Reconstructive Template - Non Absorbable
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL, FTM
Dated: May 16, 2016
Received: May 17, 2016

Dear Dr. MacFarlane:

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 Industry and Consumer Education 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 Industry and Consumer Education 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.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153632

Device Name
Endoform® Reconstructive Template - Non Absorbable

Indications for Use *(Describe)*
Endoform® Reconstructive Template -Non Absorbable 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 or bridging 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.

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510(k) Summary

Endoform® Reconstructive Template – Non-Absorbable

Submitted By: Aroa Biosurgery, Limited
2 Kingsford Smith Place
Auckland 2022
New Zealand

Contact Person: Brian R. Ward
Chief Executive Officer
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Date Prepared: 16 June 2016

Device Information:

Trade Name: Endoform® Reconstructive Template – Non-Absorbable
Common or Usual Name: Surgical Mesh
Classification Name: Mesh, Surgical (21 CFR §878.3300)
Product Code: FTL
FTM

Predicate Device: Ovine Tissue Matrix (K141053)

Reference Device: Endoform Reconstructive Template (K130547, K153633)

Device Description:

Endoform Reconstructive Template – Non-Absorbable is a surgical mesh manufactured by layering sheets of ovine forestomach matrix (OFM) to create 1- through 10- ply embroidered devices for soft tissue reconstruction. The device design includes thicknesses from 1- through 10- ply to give a range of strengths as required for a particular implant procedure. The construction of Endoform™ Reconstructive Template - Non-Absorbable devices includes lyophilization of single sheets of OFM followed by embroidery with polypropylene. Devices are terminally sterilized by ethylene oxide (EO) sterilization.

Intended Use:

Endoform Reconstructive Template – Non-Absorbable 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 or bridging material to obtain the desired surgical outcome.

Summary of Technological Characteristics:

Device	**Endoform Reconstructive Template Non-Absorbable (Subject Device)**	**Ovine Tissue Matrix OTM (Predicate Device)**	**Endoform Reconstructive Template ERT (Reference Device)**
510(k) Number	K153632	K141053	K130547/K153633
Manufacturer	Aroa Biosurgery, Ltd.	TELA Bio, Inc.	Aroa Biosurgery, Ltd.
Regulation Number	878.3300	878.3300	878.3300
Product Code	FTM	FTM	FTM
Intended Use	Intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists.	Intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists.	Intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists.
Materials	Ovine derived collagen and associated extracellular matrix components Collagen I Collagen III Polypropylene (PP)	Ovine derived collagen and associated extracellular matrix components Collagen I Collagen III Polypropylene (PP)	Ovine derived collagen and associated extracellular matrix components Collagen I Collagen III Polyglycolic Acid (PGA)
Presentation	Lyophilized sheets provided in a peel pouch	Hydrated sheets provided in a peel pouch	Lyophilized sheets provided in a peel pouch
Design	Terminally sterilized	Terminally sterilized	Terminally sterilized
Size	Up to 20 x 20 cm, 400 cm^2	Up to 25 x 40 cm, 1000 cm^2	Up to 20 x 20 cm, 200 cm^2
Thickness	Approx. 0.15-1.5 mm	Approx. 0.15-1.2 mm	Approx. 0.15-1.2 mm

Biocompatibility Data:

Biocompatibility, biomechanical bench, and *in vivo* performance testing have been conducted to evaluate the safety and performance characteristics of Endoform Reconstructive Template – Non-Absorbable.

Additional cytotoxicity testing, a toxicological assessment, and a viral inactivation assessment were performed to evaluate the safety of the modified ERT device. Results indicate that the device biocompatibility profile is acceptable.

Performance Data:

Biomechanical testing included uniaxial tensile strength (modulus of elasticity), ball burst strength, and suture retention strength. Results indicate that Endoform Reconstructive Template – Non-Absorbable is equivalent to the predicate device and meets the requirements for the intended use.

An *in vivo* study demonstrated the safety and effectiveness of Endoform Reconstructive

Template – Non-Absorbable in a model of soft tissue reinforcement.

Clinical Data:

No clinical data was submitted to support the safety and effectiveness of the subject device.

Conclusion:

Endoform Reconstructive Template – Non-Absorbable is substantially equivalent to TELA Bio's Ovine Tissue Matrix (K141053), which has been cleared by FDA for the same intended use and indications. In addition, Endoform Reconstructive Template – Non-Absorbable has similar technological characteristics and principle of operation as the predicate device.

The minor technological differences between Endoform Reconstructive Template – Non-Absorbable and the predicate device do not raise new questions of safety and effectiveness. Performance and preclinical data demonstrate that Endoform Reconstructive Template – Non-Absorbable is as safe and effective as the predicate device.