DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 20, 2016

Aroa Biosurgery
c/o Gordon MacFarlane, Ph.D., RAC
ICON PLC
62 Forest Street, Suite 300
Marlborough, MA 01752

Re: K162461
Trade/Device Name: Endoform Plastics and Reconstructive Matrix
Regulation Number: 21 CFR §878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: November 17, 2015
Received: November 21, 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)*
K162461

Device Name
Endoform® Plastics and Reconstructive Matrix

Indications for Use *(Describe)*
Endoform® Plastics and Reconstructive Matrix is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.

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

510(k) Summary for the Aroa Biosurgery Endoform® Plastics and Reconstructive Matrix (per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

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

Contact Person: Tina O'Brien
Director, Regulatory Affairs
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Telephone: +64 9 8693035

Date Prepared: August 19, 2016

2. DEVICE NAME

Proprietary Name:	Endoform® Plastics and Reconstructive Matrix
Common/Usual Name:	EndoGraft
Device Class:	Surgical Mesh
Product Code:	FTM

3. PREDICATE / REFERENCE DEVICES

Predicate Device:

- SIS Plastic Surgery Matrix (Cook Biotech) (K034039)
- Biodesign Sling, Biodesign Plastic Surgery Matrix, Biodesign Anal Fistula Plug (K161221)

Reference Devices:

- Endoform® Reconstructive Template (Aroa Biosurgery) (K130547/K156366)

4. DEVICE DESCRIPTION

Endoform® Plastics and Reconstructive Matrix is an advanced collagen matrix comprised of natural >70%, non-reconstituted collagen. Endoform® Plastics and Reconstructive Matrix is designed to be fixed, via sutures, staples or tacks to the surrounding tissue, at the discretion of the attending physician for applications in plastic and reconstructive surgery.

For example, the device can be surgically implanted to reinforce damaged or ruptured soft tissue membranes and reinforce muscle flaps. The device is supplied sterile and dry in a variety of sizes and thicknesses, which can be trimmed by surgeons to meet the individual patient's needs.

Endoform® Plastics and Reconstructive Matrix is laminated via a proprietary process termed 'lug lamination', which is a physical means of fabricating the devices, such that the individual sheets of the device are physically bonded to one another as opposed to using embroidery to sew the laminate of collagen matrix sheets.

5. INDICATIONS FOR USE

Endoform® Plastics and Reconstructive Matrix is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

The predicate and reference devices are listed in the table below. The predicate and reference devices serve to support substantial equivalence for the technological characteristics. The technological characteristics of Endoform® Plastics and Reconstructive Matrix and SIS Plastic Surgery Matrix are equivalent in that they are both primarily composed of mammalian collagens and are indicated for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery.

Side-by-Side Comparison of the Proposed Device and the Predicate and Reference Devices

Device Status	**Proposed Device**	**Predicate**	**Predicate**	**Reference Predicate**
Manufacturer	**Aroa**	**Cook Biotech**	**Cook Biotech**	**Aroa**
510K Number	Proposed	K034039	K161221	K130547/K153633
Device name	Endoform® Plastics & Reconstruction Matrix	SIS Plastic Surgery Matrix	Biodesign Plastic Surgery Matrix	Endoform® Reconstructive Template
Classification Name	Surgical mesh (FTM) 21 CFR 878.3300 Class II	Surgical mesh (FTM) 21 CFR 878.3300 Class II	Surgical mesh (FTM) 21 CFR 878.3300 Class II	Surgical mesh (FTL/FTM) 21 CFR 878.3300 Class II
Intended use	Endoform® Plastics and Reconstructive Matrix is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in	The SIS Plastic Surgery Matrix is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery.	For implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic or reconstructive surgery.	Endoform® Reconstructive Template is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include, but are not limited to the

Device Status	Proposed Device	Predicate	Predicate	Reference Predicate
Manufacturer	**Aroa**	**Cook Biotech**	**Cook Biotech**	**Aroa**
	plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.	The device is supplied sterile and is intended for one-time use.		following procedures; hernioplasty and repair of body wall defects. The device allows reinforcement or bridging of a deficit to obtain the desired surgical outcome. Endoform® Reconstructive Template is intended for single use only.
Animal origin	Ovine	Porcine	Porcine	Ovine
Tissue type	Forestomach	Small intestinal submucosa	Small intestinal submucosa	Forestomach
Nominal sizes	Sizes ranging from 1 cm^2 to 400 cm^2, lugged	2 to 70 mm width up to 200 mm length	2 to 70 mm width up to 200 mm length	Sizes ranging up to 400 cm^2
Thickness	0.15 – 1.5 mm	0.1 – 1.5 mm	100 to 1500 μm thick	Approximately 0.15 – 1.20 mm
Presentation	Sterile, lyophilized, multi-laminate lugged sheets in a peel pouch	The device is supplied sterile in double pouch system.	The device is supplied sterile in double pouch system.	Sterile, lyophilized sheets in peel pouch
Components	Ovine derived collagen	Porcine derived collagen	Porcine derived collagen an	Ovine derived collagen and polyglycolic acid (PGA) suture material

The technological characteristics of Endoform® Plastics and Reconstructive Matrix and the reference device Endoform® Reconstructive Template are equivalent in that they are both primarily composed on ovine (‘sheep’) collagen and indicated for implantation for soft tissue repair or reinforcement in plastic and reconstructive surgery. Both surgical mesh devices are manufactured from the same ovine source material using an identical manufacturing process.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Bench testing was conducted on the Endoform® Plastics and Reconstructive Matrix to support the substantial equivalence of the proposed device to the predicate device, as detailed below:

- tensile strength
- suture retention
- biochemical composition
- endotoxin
- dimensional verification
- ball burst
- modulus of elasticity
- delamination evaluation

In addition to bench testing, validation of the manufacturing process, labeling, packaging transportation, and sterilization to achieve a sterility assurance level (SAL) of 10^{-6} were performed. Results of the testing demonstrate that the proposed device meets all product specifications for the intended use.

Biocompatibility of the proposed device has been assessed via ISO 10993-1 and has been concluded that the device is biocompatible based on the established safety of the reference device.

As the proposed predicate and reference devices are technologically equivalent, safety and performance of the proposed device is based on the *in vivo* performance of the predicate and reference devices.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

There was no clinical testing required to support the indications for use as they are equivalent to the predicate device.

9. SUMMARY OF OTHER INFORMATION

No additional information was provided.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on the non-clinical and animal testing completed, and the comparisons with the predicate and reference devices, Endoform® Plastics and Reconstructive Matrix does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.