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

March 15, 2016

Aroa Biosurgery Ltd.
c/o Dr. Gordon MacFarlane
ICON plc
62 Forest Street
Marlborough, MA 01752

Re: K153633
Trade/Device Name: Endoform Reconstructive Template
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: February 16, 2016
Received: February 18, 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K153633

Device Name
Endofonn Reconstructive Template

Indications for Use *(Describe)*
Endoform Reconstructive Template is intended for usc 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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Special 510(k) Summary

510(K) NUMBER: K153663

Special 510(k) Summary for the Endoform® Reconstructive Template

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

Contact Person: Brian R. Ward
Chief Executive Officer
Brian.ward@aroabio.com
P. +64.9.8693035

Date Prepared: March 14, 2016

Device Information:

Trade Name:	Endoform® Reconstructive Template (ERT)
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical (21 CFR §878.3300, Product Code FTM)

Predicate Device: Endoform Reconstructive Template (K130547)

Device Description:
The Aroa Endoform Reconstructive Template ("ERT") is a surgical mesh manufactured by layering sheets of ovine forestomach matrix (OFM) to create 1- through 10- ply embroidered devices for implant applications as part of soft tissue reconstruction. The device design includes a range of thicknesses from 1- through 10- ply to give a range of strengths as required for a particular implant procedure. The construction of ERT devices includes lyophilization of single sheets of OFM followed by embroidery with polyglycolic acid (PGA). Devices are terminally sterilized by ethylene oxide (EO) sterilization. The device has received FDA clearance (K130547) for sizes up to 200cm^2.

Intended Use:
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 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 Similarities and Differences in Technological Characteristics, Performance and Intended Use:
The proposed change to the Endoform Reconstructive Template device is a line extension to increase the maximum device size to 400cm^2. The Endoform Reconstructive Template maintains the same intended use and fundamental technological characteristics as the predicate device including material composition, biocompatibility, sterilization, and packaging materials and processes.

The proposed device will differ only in the maximum device size available by area from 200cm^2 to 400cm^2. Performance and validation testing executed based on risk analysis of the proposed change supports the substantial equivalence of the proposed device for the intended use. The product specifications for the device have not changed as a result of the modification.

Performance Data:
Bench testing and validation testing was performed on the Endoform Reconstructive Template to support the substantial equivalence of the proposed device to the predicate device. Bench testing included mechanical strength, endotoxin, and dimensional verification testing. All bench testing was conducted under Design Control procedures. 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.

Previous biocompatibility testing performed for the product presented in K130547 is applicable to the proposed Endoform Reconstructive Template product based on the equivalence of the material composition of the proposed device to the predicate.

Clinical Data:
No clinical data was submitted to support the safety and effectiveness of the modified Endoform Reconstructive Template.

Other Information:
No other information was submitted.

Conclusion:
The technological characteristics of the proposed device are equivalent to the predicate. Performance of the device is not dependent on size, and size is the only change between the proposed device and the predicate. Based on the results of verification and validation testing it can be concluded that the proposed device is substantially equivalent to the predicate device and does not raise new questions of safety or effectiveness.