December 4, 2018

Aroa Biosurgery Ltd.
Tina O'Brien
Director, Regulatory Affairs
2 Kingsford Smith Place
Airport Oaks, Auckland 2022
New Zealand

Re: K181935
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: September 3, 2018
Received: September 5, 2018

Dear Tina O'Brien:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181935

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

Contact person/submitter	Tina O'Brien Director of Regulatory Affairs Aroa Biosurgery Ltd.
Date prepared	3 December 2018
Contact details	2 Kingsford Smith Place Airport Oaks, Auckland 2022, New Zealand +64 9 369 3035, ext. 214
Trade name	Endoform® Reconstructive Template – Non-Absorbable
Common name	Surgical mesh
Classification name	Mesh, Surgical; Mesh, Surgical Polymeric
Predicate device	Endoform® Reconstructive Template (K153632)

Device Description

Endoform Reconstructive Template – Non-Absorbable is a surgical mesh manufactured by layering sheets of ovine forestomach matrix to create multi-layer configurations of devices laminated with non-resorbable polypropylene (PP) suture material in a variety of sizes for use in soft tissue reconstruction. Devices up to 400 cm^2 are available in thicknesses from 1- through 10- ply, and larger devices up to 1000cm^2 are available in 4-, 6-, and 8-ply presentations.

Intended Use and Indications for Use

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

Endoform Reconstructive Template – Non-Absorbable is indicated for use in the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome.

Technological Characteristics Comparison

The proposed change to the Endoform Reconstructive Template device is a line extension to devices embroidered with non-resorbable polypropylene suture (K153632) to increase the maximum device size to 1000cm^2 for presentations comprised of 4, 6, and 8 layers of tissue. The modified Endoform Reconstructive Template maintains the same intended use and fundamental technological characteristics as the predicate device with polypropylene suture with respect to material composition, biocompatibility, sterilization, and packaging materials and processes.

The modified device is comprised of three (3) pieces of embroidered material, which are joined together creating 2 seams. The pieces used for fabrication have a

different embroidery pattern around the perimeter than commercial devices to facilitate the joining process. With the exception of the seaming overlaps, the modified device has the same thickness as the predicate device.

The modified device differs only in the maximum device size available by area from 400cm^2 to 1000cm^2. Performance and validation testing executed based on risk analysis of the proposed change supports substantial equivalence of the proposed device for the intended use. The performance specifications for the device have not changed as a result of the modification.

Non-Clinical Performance Data

Bench testing and validation was conducted on the larger size Endoform Reconstructive Template Non-Resorbable devices to demonstrate substantial equivalence to the predicate device. Bench testing included mechanical strength, endotoxin, and dimensional verification testing. Results of the testing confirms that the proposed device meets all product specifications for the intended use.

Previous biocompatibility testing performed for the product presented in K153632 remains applicable to the larger Endoform Reconstructive Template – Non-Absorbable product based on the equivalence of the material composition of the proposed device to the predicate.

Clinical Performance Data

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

Conclusions

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.