November 17, 2017

Aroa Biosurgery
Tina O'Brien
Director, Regulatory Affairs
2 Kingsford Smith Place
Airport Oaks, 2022 NZ Auckland

Re: K172318
Trade/Device Name: Endoform Silver Dermal Template
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 31, 2017
Received: August 1, 2017

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. 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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)*

Device Name
Endoform Silver Dermal Template

Indications for Use *(Describe)*
Endoform Silver Dermal Template is supplied sterile and is intended for single use in the management of the following wounds:
* partial and full-thickness wounds
* pressure ulcers
* venous ulcers
* diabetic ulcers
* chronic vascular ulcers
* tunnelled / undermined wounds
* surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
* trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
* draining wounds

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.

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5. 510(k) Summary

Contact person/submitter	Tina O'Brien Director of Regulatory Affairs Aroa Biosurgery
Author	Amelia Ortiz Regulatory & Quality Engineer
Date prepared	31 July 2017
Contact details	2 Kingsford Smith Place Airport Oaks Auckland 2022, New Zealand +64 9 369 3035
Trade name	Endoform Silver Dermal Template
Common name	Dressing, wound, drug
Predicate device	PriMatrix Ag Antimicrobial Dermal Repair Scaffold (K100261)
Reference device	Endoform Dermal Template (K092096)

5.1. Device Description

Endoform Silver Dermal Template (Endoform Silver) is an advanced wound care dressing primarily composed of natural, non-reconstituted collagen retaining the native extracellular matrix associated macromolecules including fibronectin, glycosaminoglycans, laminin, and elastin. Endoform Silver is supplied as sterile intact or fenestrated sheets.

Endoform Silver contains approximately 12 µg/cm² (~0.3% w/w) ionic silver, intended to prevent microbial colonization of the dressing. The dressing is effective against a broad spectrum of microbes, including *Acinetobacter baumannii*, *Candida parapsilosis*, *Candida glabrata, Candida albicans*, *Escherichia coli*, Methicillin Resistant *Staphylococcus aureus* (MRSA), coagulase-negative *Staphylococci*, group A (beta-hemolytic) *Streptococci*, *Pseudomonas aeruginosa*, *Aspergillus niger*, and Vancomycin Resistant *Enterococci* (VRE). The dressing provides sustained antimicrobial effectiveness within the dressing for up to 7 days.

Endoform Silver is derived from ovine (sheep) extracellular matrix and it retains the innate biological structure of the native extracellular matrix. When rehydrated with exudate or sterile saline, Endoform Silver transforms into a soft conforming sheet, which is naturally incorporated into the wound over time.

5.2. Intended Use and Indications for Use

5.2.1. Intended Use

Endoform Silver Dermal Template is a sterile, single use ovine forestomach-derived extracellular matrix intended to cover, protect, and provide a moist wound environment.

5.2.2. Indications for Use

Endoform Silver Dermal Template is supplied sterile and is intended for single use in the management of the following wounds:

- partial and full-thickness wounds
- pressure ulcers
- venous ulcers
- diabetic ulcers
- chronic vascular ulcers
- tunnelled / undermined wounds
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric,
- wound dehiscence)
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- draining wounds

5.3. Technological Characteristics Comparison

The addition of ionic silver to the currently cleared reference device, Endoform Dermal Template (K092096), results in a new device (Endoform Silver) that is substantially equivalent to the predicate in terms of preventing microbial colonization of the device when used within identical indications for use, based on in vitro performance testing.

The primary differences between Endoform Silver and the predicate, PriMatrix Ag Antimicrobial Dermal Repair Scaffold, are the raw material origin and the tissue type.

Table 5-1 Technological Characteristics Comparison

	Subject Device Endoform Silver Dermal Template	**Predicate Device** PriMatrix Ag Antimicrobial Dermal Repair Scaffold (K100261)	**Reference Device** Endoform Dermal Template (K092096)
Manufacturer	**Aroa**	**TEI Biosciences**	**Aroa**
510K Number	-	K100261	K092096
Device name	Endoform Silver Dermal Template	PriMatrix Ag Antimicrobial Dermal Repair Scaffold	Endoform Dermal Template
Classification Name	Dressing, wound, drug (FRO) Unclassified	Dressing, wound, drug (FRO) Unclassified	Dressing, wound, collagen (KGN) Unclassified

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Endoform Silver Dermal Template – Traditional 510(k)

	Subject Device Endoform Silver Dermal Template	**Predicate Device** PriMatrix Ag Antimicrobial Dermal Repair Scaffold (K100261)	**Reference Device** Endoform Dermal Template (K092096)
Intended use	Endoform Silver Dermal Template is a sterile, single use ovine forestomach-derived extracellular matrix intended to cover, protect, and provide a moist wound environment.	Primatrix Ag Antimicrobial Dermal Repair Scaffold is intended for the management of wounds that include: *Partial and full thickness wounds *Pressure, diabetic and venous ulcers *Second-degree burns *Surgical wounds- donor sites/grafts, post Moh's surgery, post-laser surgery, podiatric, wounds dehiscence *Trauma wounds- abrasions, lacerations, and skin tears *Tunneled/undermined wounds *Draining wounds	Endoform Dermal Template is supplied sterile and is intended for single use in the treatment of the following wounds: * partial and full-thickness wounds * pressure ulcers * venous ulcers * diabetic ulcers * chronic vascular ulcers * tunneled / undermined wounds * surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) * trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) * draining wounds
Indications for Use	Endoform Silver Dermal Template is supplied sterile and is intended for single use in the management of the following wounds: * partial and full-thickness wounds * pressure ulcers * venous ulcers * diabetic ulcers * chronic vascular ulcers * tunneled / undermined wounds * surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) * trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) * draining wounds	Primatrix Ag Antimicrobial is intended for the management of wounds that include: *Partial and full thickness wounds *Pressure, diabetic and venous ulcers *Second-degree burns *Surgical wounds- donor sites/grafts, post Moh's surgery, post-laser surgery, podiatric, wounds dehiscence *Trauma wounds- abrasions, lacerations, and skin tears *Tunneled/undermined wounds *Draining wounds	Endoform Dermal Template is supplied sterile and is intended for single use in the treatment of the following wounds: * partial and full-thickness wounds * pressure ulcers * venous ulcers * diabetic ulcers * chronic vascular ulcers * tunneled / undermined wounds * surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) * trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) * draining wounds
Animal origin	Ovine	Bovine	Ovine
Tissue type	Forestomach	Dermis	Forestomach
Nominal sizes	2x2" and 4x5" fenestrated or non-fenestrated sheets	Fenestrated, non-fenestrated, or meshed sheets ranging from 4x4 cm to 10x25cm.	Fenestrated or non-fenestrated sheets

	Subject Device Endoform Silver Dermal Template	**Predicate Device** PriMatrix Ag Antimicrobial Dermal Repair Scaffold (K100261)	**Reference Device** Endoform Dermal Template (K092096)
			ranging in size up to 400 cm^2
Thickness	0.3 ±0.1 mm	0.65mm	0.25±0.01 mm
Presentation	Sterile, lyophilized single sheets in peel pouch	Sterile, single sheets	Sterile, lyophilized single sheets in peel pouch
Components	Ovine derived collagen and associated ECM components -collagen I -collagen III	Bovine derived collagen and associated ECM components -collagen I -collagen III	Ovine derived collagen and associated ECM components -collagen I -collagen III
Sterilization method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Antimicrobial content	Ionic Silver approximately 12 µg/cm^2	Ionic Silver ≤165 µg/cm^2	N/A, device is not antimicrobial
Storage conditions	Room temperature	Room temperature (15-30ºC)	Ambient temperature

5.4. Non-Clinical Performance Data

Based on *in vitro* performance testing, antimicrobial effectiveness of the dressing and wear time testing conducted against a panel of clinically relevant microbial species demonstrates that the device inhibits microbial colonization of the dressing.

Tested micro-organisms included:

- *Acinetobacter baumannii*
- *Candida albicans*
- *Candida parapsilosis*
- *Candida glabrata*
- *Escherichia coli*
- Methicillin Resistant *Staphylococcus aureus* (MRSA)
- *Staphylococcus epidermidis*
- *Streptococcus pyrogenes*
- *Pseudomonas aeruginosa*
- *Aspergillus niger*
- Vancomycin Resistant *Enterococci* (VRE)

The results of in vitro testing verify the antimicrobial silver in the device is effective in inhibiting microbial colonization of the dressing, with antimicrobial effectiveness within the dressing sustained for up to 7 days.

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Endoform Silver Dermal Template – Traditional 510(k)

Performance bench testing was completed on various device characteristics to ensure product requirements were satisfied, as well as for comparison against the predicate product. The acceptance criteria were met for all characteristics and comparison against the predicate and reference devices demonstrates equivalent performance. Performance tests included:

- Physical characteristics
  Uniaxial strength, burst strength, thickness, dimensions, permeability, rehydration rate, melt onset temperature

- Composition
  Collagen, GAGs, DNA, fibronectin, laminin, silver concentration, moisture content

- Endotoxin levels were tested in accordance with ANSI/AAMI ST72 - Bacterial Endotoxins –Test Methodologies, routine monitoring, and alternatives to batch testing and USP 39-NF34:2016 <85> Bacterial Endotoxin Test

- To ensure an SAL of 10^{-6}, sterilization validation was conducted in accordance with ISO 11135 Sterilization of health care products—Ethylene Oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices; ISO 11737-1 Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microogranisms on Products; and ISO 11737-2 Sterilisation of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilisation process

- Sterile packaging was evaluated for seal integrity and seal strength against ISO 11607–1 Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging, and ISO 11607–2 Packaging for Terminally Sterilized Medical Devices Part 2: Validation Requirements for Forming, Sealing and Assembly Process.

- Shelf life testing was conducted under accelerated and real time aging conditions to ensure the stability of the biophysical and biochemical characteristics, as well as antimicrobial effectiveness in accordance with ISO 20743: 2013 Textiles -- Determination of antibacterial activity of textile products.

- Biocompatibility was assessed for cytotoxicity, sensitization, irritation, systemic toxicity, sub-acute toxicity, genotoxicity, implantation, hemocompatibility, chronic toxicity, carcinogenicity, reproductive and developmental toxicity, biodegradation, toxicokinetics, and immunotoxicity in accordance with ISO 10993-1 Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. Assessment results conclude that the device presents no new risk to end-users.

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.

5.5. Clinical Performance Data

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

5.6. Conclusions

The Endoform Silver Dermal Template is substantially equivalent to the PriMatrix Ag Antimicrobial Dermal Repair Scaffold (K100261) device. Bench performance testing demonstrates the two devices are substantially equivalent for their intended use.