July 29, 2020

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

Re: K200413
Trade/Device Name: Symphony
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 24, 2020
Received: June 29, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Anjana Jain, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K200413

Device Name

Symphony™

Indications for Use *(Describe)*

Symphony™ is indicated for 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.

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5 510(k) Summary

Contact person/submitter	Tina O'Brien Director of Regulatory Affairs Aroa Biosurgery Ltd.
Date prepared	18 February 2020
Contact details	2 Kingsford Smith Place Airport Oaks, Auckland 2022, New Zealand +64 9 369 3035, ext. 214
Trade name	Symphony™
Common name	Wound dressing
Classification	Unclassified
Classification name	Dressing, Wound, Collagen
Product Code	KGN
Predicate device	Endoform® Topical Matrix (K171231)

5.1 Device Description

Symphony™ is a sterile, single use wound dressing manufactured by incorporating a layer of glycosaminoglycans between sheets of ovine forestomach-derived extracellular collagen matrix. The 4-ply rectangular devices are available in sizes up to 200 cm^2.

5.2 Intended Use

Symphony™ is intended to cover, protect, and provide a moist wound environment.

5.3 Indications for Use

Symphony™ is indicated for 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

5.4 Technological Characteristics Comparison

Symphony™ devices are part of the Endoform® Dermal Template family of devices to introduce new configurations that include a layer of glycosaminoglycans. Symphony™ maintains the same fundamental technological characteristics as the predicate device with respect to ovine forestomach material, sterilization method, packaging materials, and tissue processing.

The Symphony™ device differs from the predicate only with respect to the addition of a layer of glycosaminoglycans. The devices are available in a variety of sizes. Performance and validation testing executed based on risk analysis of the design changes supports substantial equivalence of the subject device.

The table below summarizes the similarities and differences:

Parameter	Subject Device – Symphony™	Predicate Device- Endoform® Topical Matrix
Indications for Use	Symphony™ is indicated for 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	Endoform® Topical Matrix is indicated for 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
Animal Origin	Ovine	Ovine
Tissue Type	Forestomach	Forestomach
Presentation – ply's	Device are lugged and comprised of 4 layers as follows: • OFM • OFM • GAG Foam • OFM	Devices are lugged and comprised of 2-, 3-, 4- and 5-layers of OFM (1-layer is fenestrated)
Presentation - sizes	Finished devices have the following sizes • 2.5 cm x 2.5 cm • 5 cm x 5 cm • 10 cm x 10 cm • 10 cm x 20 cm	Sizes ranging from 1 cm^2 to 400 cm^2
Thickness	≥0.35 mm	1-ply ≥ 0.05mm;

Parameter	Subject Device – Symphony™	Predicate Device- Endoform® Topical Matrix
		2-ply ≥ 0.20mm; 3-ply ≥ 0.35mm; 4-ply ≥ 0.50mm; 5-ply ≥ 0.65mm
OFM Content (% total mass)	55% - 80% w/w	100% w/w
Final device moisture content (%w/w)	≤30% w/w total mass	≤30% w/w total mass
Collagen concentration of OFM (% total mass)	≥70% w/w	>70% w/w
Onset Melt Temperature of OFM (°C)	55-70 °C	55-70 °C
Moisture content of OFM (% total mass)	<30% w/w	<30% w/w
Total Sulphated GAGs' concentration of OFM (mg/g)	>0.05 mg/g	>0.05 mg/g
OFM Basement membrane remnants (laminin)	Present	Present
OFM Fibronectin	Present	Present
DNA concentration of OFM (mg/g)	<2.1 mg/g	<2.1 mg/g
GAG foam (% total mass)	20% - 45% w/w	Not applicable – the predicate device does not contain GAG foam (0%)
Permeability (permeability Index, PI)	PI>0	PI>0
Suture Retention	≥1.5 N	≥1.5 N
Endotoxin	<20 EU/device	<20 EU/device
EDTA Residuals (mg/kg)	<11000 mg/kg	<11000 mg/kg
TX-100 Residuals (mg/kg)	<15700 mg/kg	<15700 mg/kg
Bioburden	<1000 CFU/device	<1000 CFU/device
Laminate Stability	Hydrated device maintains laminate integrity after 10 minutes hydration and continuous handling	Hydrated device does not delaminate after 5 minutes of handling
Modulus of elasticity	<0.1 GPa	<0.1 GPa
Rehydration Time (seconds)	< 5 min (300 seconds)	< 5 min (300 seconds)

5.5 Non-Clinical Performance Data

Bench testing conducted included GAG foam characteristics, physical specifications, mechanical strength, endotoxin, and dimensional verification testing. Results of the testing confirms that the proposed device meets all product specifications for the intended use and demonstrates substantial equivalence to the predicate device.

The following biocompatibility testing was conducted in accordance with ISO 10993-1 based on the device's classification as 'breached or compromised surface' contact for a 'permanent' duration:

- Cytotoxicity (MEM Elution)
- Delayed Type Hypersensitivity (Sensitization)
- Irritation (intracutaneous reactivity)
- Implantation
- Toxicological risk assessment

5.6 Conclusions

The technological characteristics of the proposed device are similar to the predicate. Performance of the device is not impacted by the addition of GAGs or the layer configuration. 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.