March 31, 2021

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

Re: K200502
Trade/Device Name: Myriad Particles
Regulatory Class: Unclassified
Product Code: KGN
Dated: February 25, 2021
Received: March 1, 2021

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,

Lixin Liu, 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

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)*

K200502

Device Name
Myriad™ Particles

Indications for Use *(Describe)*

Myriad™ Particles 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
- tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- trauma wounds (abrasions, lacerations, partial-thickness 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.
Last Updated	30 March 2021
Contact details	2 Kingsford Smith Place Airport Oaks, Auckland 2022, New Zealand +64 9 369 3035, ext. 214
Trade name	Myriad™ Particles
Common name	Wound dressing
Classification	Unclassified
Classification name	Dressing, Wound, Collagen
Product code	KGN
Predicate device	Endoform™ Dermal Template (K092096)
Reference device	Cook® ECM Powder (K152033)

5.1 Device Description

Myriad™ Particles is derived from an extracellular matrix primarily composed of ovine collagen and is supplied as a sterile particulate.

5.2 Intended Use

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

5.3 Indications for Use

Myriad™ Particles 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
- tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- trauma wounds (abrasions, lacerations, partial-thickness bums, and skin tears)
- draining wounds

5.4 Technological Characteristics Comparison

The primary difference between the subject and predicate devices is the device presentation (powder vs. sheet format). An additional inner tray has been implemented to facilitate dispensing of the new device presentation.

The subject Myriad™ Particles® device is identical to the predicate Endoform™ Dermal Template with respect to raw material, tissue processing (with the exception of the steps to convert the ECM material from a sheet to a particulate), terminal sterilization, intended use, and indications for use.

Cook Biotech's ECM Powder (K152033) is noted as a reference device to highlight a similar design modification to a 510(k) cleared animal-derived collagen dressing sheet format to a powdered form, both intended for use in wound care.

Device	**Subject Device** Myriad™ Particles (K200502)	**Predicate Device** Endoform™ Dermal Template (K092096)
Manufacturer	Aroa Biosurgery Ltd.	Aroa Biosurgery Ltd.
Classification Name	dressing, wound, collagen (KGN) Unclassified	dressing, wound, collagen (KGN) Unclassified
Intended Use	Myriad™ Particles is intended to cover, protect, and provide a moist wound environment.	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 • 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
Indications for Use	Myriad™ Particles 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 • tunneled/undermined wounds • Surgical wounds (donor sites/grafts, post-Moh's surgery,	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 • tunnelled / undermined wounds

Device	**Subject Device** Myriad™ Particles (K200502)	**Predicate Device** Endoform™ Dermal Template (K092096)
	post-laser surgery, podiatric, wound dehiscence) • trauma wounds (abrasions, lacerations, partial-thickness bums, and skin tears) • draining 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 Tissue	Ovine Forestomach	Ovine Forestomach
Nominal sizes	Particles ranging from 0.25 mm –2.00 mm	Fenestrated or non-fenestrated sheets ranging in size up to 400 cm^2
Components	Ovine derived collagen and associated ECM components -collagen I -collagen III	Ovine derived collagen and associated ECM components -collagen I -collagen III
Bioburden (CFU/device)	<1000 CFU/device	<1000 CFU/device
Collagen (% total mass)	>70%	80-90 %
DNA (mg/g)	<2.1 mg/g	<2.1 mg/g
Endotoxin (EU/device)	<20 EU/device	<20 EU/device
Ethylene oxide residues(mg/device)	EO <4 mg /device ECH <9 mg/device	EO <0.2 mg/device ECH <0.45 mg/ device
Fibronectin	Present	Present
Glycosaminoglycans (mg/g)	>0.05 mg/g	>0.05 mg/g
Laminin	Present	Present
Moisture content (% totalmass)	< 30% w/w	< 30% w/w
Onset Melt Temperature	55-70 °C	55-70 °C
Particle size	Particles must be able to pass through a 3.15 mm aperture calibrated sieve (ISO 3310-1) whenvibratory sieved.	N/A
Permeability	Permeability Index >0	Permeability Index >0
Process chemical residues(g/kg)	EDTA <11 g/kg TX-100 <15.7 g/kg	EDTA <425 g/kg TX-100 <610 g/kg
Process heavy metal residues (mg/kg)	Cr <650 mg/kg Fe <1,150 mg/kg Ni <150 mg/kg	N/A
Rehydration Time	< 1 min	< 1 min
Sterility Assurance Level(SAL)	10^{-6}	10^{-6}

5.5 Non-Clinical Performance Data

Bench testing included physical specifications, packaging, EO residuals, bioburden, and endotoxin 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
- Heavy metal testing

5.6 Clinical Performance Data

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

5.7 Conclusions

Myriad™ Particles is as safe and effective and has the same intended uses, indications, and principles of operation as Endoform™ Dermal Template. The minor differences between the Myriad™ Particles presentation and the predicate device do not raise different questions of safety or effectiveness. Performance data demonstrate that Myriad™ Particles is as safe and effective as the predicate device.