February 2, 2024

StimLabs, LLC
Melissa O'Connor
Chief Quality and Regulatory Affairs Officer
1225 Northmeadow Parkway, Suite 104
Roswell, Georgia 30076

Re: K231325
Trade/Device Name: Corplex P/Theracor P/Allacor P
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 2, 2024
Received: January 3, 2024

Dear Melissa O'Connor:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231325

Device Name
Corplex P/Theracor P/Allacor P

Indications for Use *(Describe)*
Corplex P/Theracor P/Allacor P 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1. **SUBMITTER/510(K) HOLDER:**

StimLabs, LLC, FEI# 3012823434
1225 Northmeadow Parkway, Suite 104
Roswell, Georgia 30076
Phone: (888) 346-9802
Contact Person: Melissa O'Connor, M.S., RAC, CTBS, FRAPS
Chief Quality and Regulatory Officer

Date Prepared: 02 Feb 2024

2. **DEVICE NAME:**

Trade name[1]: Corplex P/Theracor P/Allacor P
Product Code: KGN
Common name: Wound Dressing with Animal-Derived Materials
Classification name: Unclassified

3. **PREDICATE DEVICE:**

Predicate Device: Myriad Particles
Manufacturer: Aroa Biosurgery, LTD
K200502, KGN, Unclassified

Reference Device: InnovaMatrix PD
Manufacturer: Triad Life Sciences, Inc.
K211902, KGN, Unclassified

Reference Device: Prokera
Manufacturer: BioTissue, Inc.
K032104, NQB, Class II Medical Device (21 CFR 886.3130)

4. **DEVICE DESCRIPTION**

Corplex P/Theracor P/Allacor P is derived from human umbilical cord extracellular matrix (ECM) and is indicated for the management of a range of acute and chronic wounds. As a resorbable particulate device, Corplex P/Theracor P/Allacor P is lyophilized and packaged in a sterile vial, allowing the device to be rehydrated and applied directly to the wound.

5. **INTENDED USE**

Corplex P/Theracor P/Allacor P is intended to cover, protect, and provide a moist wound environment.

[1] Corplex P, Theracor P, and Allacor P are different brand names of the same product and are entirely identical with no changes or differences to product design, manufacturing, intended use, or indications for use.

6. INDICATIONS FOR USE

Corplex P/Theracor P/Allacor P 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

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALNCE

Corplex P/Theracor P/Allacor P is substantially equivalent to the predicate device, Myriad Particles (K200502) with respect to intended use, indications for use, configuration, components, moisture content, and sterility assurance level.

The primary differences between Corplex P/Theracor P/Allacor P and predicate devices are size/volume, nominal particle size, material source, collagen content (% total weight), total glycosaminoglycans (mg/g), packaging, sterilization method, and shelf life.

Triad Life Sciences' InnovaMatrix PD (K211902) and BioTissue's Prokera (K032104) are noted as reference devices to substantiate that the differences noted between Corplex P/Theracor P/Allacor P and Myriad Particles, primarily the difference in raw material source, do not raise additional questions or safety or effectiveness that have not already been mitigated by the performance, biocompatibilty and clinical testing described within this submission.

Corplex P/Theracor P/Allacor P is therefore substantially equivalent to the predicate device, Myriad Particles.

Corplex P™/Theracor P™/Allacor P™ Substantial Equivalence Table					
Sponsor	**StimLabs, LLC**	**Aroa Biosurgery, LTD**	**Comparison**	**Triad Life Sciences, Inc.**	**BioTissue, Inc**
510(k) Number	K231325	K200502	N/A	K211902	K032104
Device Name	Corplex P/Theracor P/Allacor P	Myriad Particles	N/A	InnovaMatrix PD	Prokera
Classification	Unclassified	Unclassified	Same	Unclassified	Class II, 886.3130
Product Code	KGN	KGN	Same	KGN	NQB
Size/Volume	1 cc 2 cc 4 cc	500 mg 1000 mg	Different, but does not affect safety and effectiveness.	Mass offering up to ≤ 1000 mg	Classic, Plus, Slim, Clear
Nominal Particle Sizes	Particles ranging from 0.1 mm to 2.0 mm	Particles ranging from 0.25 mm to 2.00 mm	Different, but does not affect safety and effectiveness.	Particles ≤ 1000 μm (1 mm)	OD=21.6 mm ID= 15.5 mm or 17.9 mm Height= 1.1 mm or 0.7 mm
Indications for Use	Corplex P/Theracor P/Allacor P 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)	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,	Same	InnovaMatrix™ is indicated for the management of wounds including: • partial- and full-thickness wounds, • pressure ulcers, • venous ulcers, • diabetic ulcers, • chronic vascular ulcers, • tunneled/undermined wounds, • surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), • trauma wounds (abrasions, lacerations, second-	Prokera is intended for use in eyes in which ocular surface cells are damaged or underlying stroma is inflamed or scarred and best suited to prevent adhesion of the eyelid to the ocular surface with the large ophthalmic conformer. Acting as a self-retaining biologic corneal bandage, Prokera effectively treats superficial corneal surface diseases by suppressing inflammation and related pain, promoting epithelial healing, and avoiding haze. Prokera is inserted between the eyeball and the eyelid to maintain space in the orbital cavity

	• Draining wounds	lacerations, partial-thickness burns, and skin tears) • Draining wounds		degree burns and skin tears) • draining wounds.	and to prevent closure or adhesions. Placement of the conformer also enables application of the cryopreserved amniotic membrane to the ocular surface without the need for sutures.
Configuration	Particles	Particles	Same	Particles	Cryopreserved Corneal-epithelial insert consisting of ophthalmic conformer and amniotic membrane
Material Source	Human umbilical cord (recovered per 21 CFR 1271)	Ovine forestomach	Different, but does not affect safety and effectiveness.	Porcine placenta	Human amniotic membrane (recovered per 21 CFR 1271)
Components	Collagen and associated ECM components -collagen I -collagen III -collagen V	Collagen and associated ECM components -collagen I -collagen III -collagen V	Same	Collagen, extracellular matrix	Collagen, extracellular matrix
Collagen (% total mass)	46% (Mean Value)	>70%	Similar to predicate device, ECM characterization supports substantial equivalence	Present, composed primarily of collagen	Present
Total Glycosaminoglycans (mg/g)	20.3 mg/g (Mean Value)	>0.05 mg/g	Similar to predicate device, ECM characterization supports substantial equivalence	Present	Present
Endotoxin (EU/device)	<20 EU/device	<20 EU/device	Same	Unknown	Unknown

Packaging	Glass vial with bromobutyl stopper and aluminum crimped lid, inside single peel-open pouch	Polymer blister tray with a matching lid adhered to tray lip	Different. Differences were evaluated by biocompatibility and performance testing and support SE.	Double peel-open packages	Double peel-open pouches
Sterilization	Sterilized by electron beam irradiation	Sterilized by ethylene oxide	Different, but does not affect safety and effectiveness.	Sterilized by electron beam irradiation	Aseptically processed
Moisture Content	<15%*	< 30% w/w*	Same	Unknown	Unknown
Sterility Assurance Level	10^{-6}	10^{-6}	Same	10^{-6}	N/A
Shelf Life	One Year	Unknown	Different, but does not affect safety and effectiveness.	Two Months	Two Years
Prescription or OTC	Prescription	Prescription	Same	Prescription	Prescription
Single or Multiple Use	Single Use	Single Use	Same	Single Use	Single Use

*Residual moisture is calculated by StimLabs via a chemical reaction which represents the percentage of water content remaining after lyophilization. The Predicate device measures residual moisture by weight (mass) loss and is presented as "weight per weight". The units of measurement as presented are equivalent.

8. PERFORMANCE TESTING

The following non-clinical performance testing was conducted to demonstrate substantial equivalence of Corplex P/Theracor P/Allacor P to the predicate device or to mitigate any potential performance risks related to the differences between Corplex P/Theracor P/Allacor P, the predicate, and reference devices:

Corplex P/Theracor P/Allacor P Performance Testing	
Pour Test – Dry	PASS
Solution Compatibility Test	PASS
Digestion Assay	PASS
Pour Test – Wet	PASS
Absorption Test	PASS
Evaporation Test	PASS
Extracellular Matrix Characterization	PASS

9. BIOCOMPATIBILITY TESTING

Corplex P/Theracor P/Allacor P is categorized for long term (>30 days) contact with breached and/or compromised skin surfaces. Biocompatibility testing was conducted in accordance with the US Food and Drug Administration Guidance entitled Use of International Standard ISO-10993: 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' and test results meet the requirements.

- Cytotoxicity: ISO 10993-5:2009 - Tests for in vitro cytotoxicity
- Materials Mediated Pyrogenicity: ISO 10993-11:2017 - Tests for systemic toxicity
- Sensitization: ISO 10993-10:2010 - Tests for irritation and skin sensitization
- Acute Systemic Toxicity: ISO 10993-11:2017 - Tests for systemic toxicity
- Intracutaneous Reactivity: ISO 10993-10:2021 Tests for irritation and skin sensitization
- Implantation: ISO 10993-6:2016 - Tests for local effects after implantation,
- Chemical Characterization and Toxicological Risk Assessment: ISO 10993-18:2020, ISO 10993-17:2002, ISO 21726:2019
- Genotoxicity: 10993-3:2014, ISO 10993-33:2015
- Viral Risk Assessment and Clearance Study
- Endotoxin: ANSI/AAMI/ST72, Bacterial Endotoxins - Test Methodologies, routine monitoring, and alternative batch testing
- Packaging System Cytotoxicity: ISO 10993-5:2009- Tests for in vitro cytotoxicity

10. CLINICAL TESTING

The following clinical testing was conducted to demonstrate substantial equivalence of Corplex P/Theracor P/Allacor P to the predicate device and to mitigate any potential safety risks in human subjects related to the differences between Corplex P/Theracor P/Allacor P, the predicate, and reference devices:

- Human Repeat Insult Patch Test
- Skin Prick Test

11. CONCLUSION

Corplex P/Theracor P/Allacor P has the same intended use, indications for use, configuration, components, moisture content, and sterility assurance level as Myriad Particles. The differences between Corplex P/Theracor P/Allacor P and the predicate device do not raise different questions of safety or effectiveness. The combination of performance testing, biocompatibility, and clinical testing, as well as the incorporation of reference devices to justify the differences, demonstrate that Corplex P/Theracor P/Allacor P is as safe and effective as and substantially equivalent to the predicate device.