October 18, 2024

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

Re: K242828
Trade/Device Name: Corplex P/ Theracor P/ Allacor P
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 18, 2024
Received: September 19, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242828

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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: 17 Oct 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:**

Trade name: Corplex P/Theracor P/Allacor P (K231325; Unclassified)
Product Code: KGN
Manufacturer: StimLabs, LLC

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.

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

[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.

- 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 identical to the predicate device, Corplex P/Theracor P/Allacor P (K231325) with respect to intended use, indications for use, technological characteristics, operational characteristics, components, moisture content, and sterility assurance level. A minor modification has been made to the device's design to include an 8 cc configuration. The modifications do not prevent the subject device from performing in a substantially equivalent manner to the predicate device. Based on a risk assessment, appropriate verification testing was performed, yielding acceptable results. The differences in design do not raise new questions of safety and effectiveness compared to the predicate device.

Corplex P/Theracor P/Allacor P is substantially equivalent to the predicate device.

8. VERIFICATION AND VALIDATION TESTING

The following verification testing was conducted to demonstrate substantial equivalence of Corplex P/Theracor P/Allacor P to the predicate device and to mitigate any potential risks related to the differences in design between Corplex P/Theracor P/Allacor P and the predicate device:

Corplex P/Theracor P/Allacor P Verification Testing	
Bioburden Testing	PASS

Testing was performed based on the risk assessment for the proposed change using the same methods used to support the clearance of the predicate device.

9. BIOCOMPATIBILITY TESTING

The modification to design did not raise new questions of safety or effectiveness pertaining to the biocompatibility of the subject device; therefore, biocompatibility testing was neither required nor performed.

10. CLINICAL TESTING

The modification to design did not raise new questions of safety or effectiveness pertaining to the previous clinical testing performed for the predicate device. Additional clinical testing was neither required nor performed to support demonstration of substantial equivalence.

11. CONCLUSION

Corplex P/Theracor P/Allacor P is identical to the predicate device, Corplex P/Theracor P/Allacor P (K231325) with respect to intended use, indications for use, technological characteristics, operational characteristics, components, moisture content, and sterility assurance level. The design differences raised by this modification do not raise new questions of safety or effectiveness. The verification testing

performed demonstrates that Corplex P/Theracor P/Allacor P is as safe and effective compared to the predicate and is substantially equivalent to the predicate device.

Corplex P/Theracor P/ Allacor P Substantial Equivalence Table			
Sponsor	**StimLabs, LLC**	**StimLabs, LLC**	**Comparison**
510(k) Number	K242828	K231325	N/A
Device Name	Corplex P/ Theracor P/ Allacor P	Corplex P/ Theracor P/ Allacor P	Same
Classification	Unclassified	Unclassified	Same
Product Code	KGN	KGN	Same
Size/Volume	1 cc 2 cc 4 cc 8 cc	1 cc 2 cc 4 cc	Does not raise new questions of safety and effectiveness
Nominal Particle Sizes	Particles ranging from 0.1 mm to 2.0 mm	Particles ranging from 0.1 mm to 2.0 mm	Same
Intended Use	Corplex P is intended to cover, protect, and provide a moist wound environment.	Corplex P is intended to cover, protect, and provide a moist wound environment.	Same
Indications for Use	Corplex 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	Corplex 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	Same
Configuration	Particles	Particles	Same
Material Source	Human umbilical cord (recovered per 21 CFR 1271)	Human umbilical cord (recovered per 21 CFR 1271)	Same
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 (% total weight)	46% (Mean Value)	46% (Mean Value)	Same

Total Glycosaminoglycans (mg/g)	20.3 mg/g (Mean Value)	20.3 mg/g (Mean Value)	Same
Endotoxin (EU/device)	<20 EU/device	<20 EU/device	Same
Packaging	10 mL Glass vial with bromobutyl stopper and aluminum crimped lid, inside single peel-open pouch	6 mL Glass vial with bromobutyl stopper and aluminum crimped lid, inside single peel-open pouch	Does not raise new questions of safety or effectiveness
Sterilization	Sterilized by electron beam irradiation	Sterilized by electron beam irradiation	Same
Moisture Content	<15%*	<15%*	Same
Particle Size	Particles must be able to pass through a 2.00 mm aperture calibrated sieve and not pass through a 0.106 mm aperture calibrated sieve (ASTM E11) when manually sieved.	Particles must be able to pass through a 2.00 mm aperture calibrated sieve and not pass through a 0.106 mm aperture calibrated sieve (ASTM E11) when manually sieved.	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same
Shelf Life	One Year	One Year	Same
Prescription or OTC	Prescription	Prescription	Same
Single or Multiple Use	Single Use	Single Use	Same

*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.