



December 22, 2025

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

Re: K253339

Trade/Device Name: Theracor  
Regulatory Class: Unclassified  
Product Code: KGN  
Dated: September 29, 2025  
Received: September 30, 2025

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](mailto: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 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

## Indications for Use

510(k) Number (if known)

K253339

Device Name

Theracor

Indications for Use (Describe)

Theracor 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

Secondary Contact: John Mayhall, M.S.  
Senior Regulatory Affairs Specialist

Date Prepared: **19 December 2025**

2. **DEVICE NAME:**

Trade name: Theracor  
Product Code: KGN  
Common name: Wound Dressing with Animal-Derived Materials  
Classification name: Unclassified

3. **PREDICATE DEVICE:**

Predicate Device: Corplex P/Theracor P/Allacor P  
Manufacturer: StimLabs, LLC  
K231325, KGN, Unclassified

Reference Device: Endoform Dermal Template  
Manufacturer: Mysenthes LTD  
K092096, KGN, Unclassified

4. **DEVICE DESCRIPTION**

Theracor is derived from human umbilical cord extracellular matrix (ECM) and is indicated for the management of a range of acute and chronic wounds. The device is intended to cover, protect, and provide a moist wound environment. As a resorbable device, Theracor is aseptically processed and lyophilized to remove moisture while preserving the structural components of the umbilical cord matrix. The device is packaged in sheet form and should be rehydrated prior to applying to the wound bed.

5. **INTENDED USE**

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

## 6. INDICATIONS FOR USE

Theracor 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

Theracor is identical to the predicate device, Corplex P/Theracor P/Allacor P (K231325) with respect to intended use, indications for use, materials of construction, components, moisture content, sterilization method, sterility assurance level, and shelf-life.

The primary differences between Theracor and predicate devices are the device format and packaging. These differences are minor and have been described, justified, and mitigated (to confirm that differences do not present any additional safety or efficacy concerns) by performance and safety testing conducted and described within this submission.

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

## 8. PERFORMANCE TESTING

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

Theracor Performance Testing	
Extracellular Matrix Characterization	PASS
Residual Moisture	PASS

## 9. BIOCOMPATIBILITY TESTING

Theracor 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
- Endotoxin: ANSI/AAMI/ST72, Bacterial Endotoxins - Test Methodologies, routine monitoring, and alternative batch testing

10. **CLINICAL TESTING**

Clinical testing was not conducted to demonstrate that Theracor is substantially equivalent to the predicate device.

11. **CONCLUSION**

Theracor has the same intended use, indications for use, materials of construction, components, moisture content, sterilization method, sterility assurance level, and shelf-life as Corplex P/Theracor P/Allacor P. The differences between Theracor and the predicate device do not raise different questions of safety or effectiveness. The combination of performance testing and biocompatibility testing justifies the differences and demonstrates that Theracor is as safe and effective as and substantially equivalent to the predicate device.

<b>Comparison Table Demonstrating the Substantial Equivalence of Theracor to Corplex P</b>				
<b>Sponsor</b>	<b>StimLabs, LLC</b>	<b>StimLabs, LLC</b>	<b>Comparison</b>	<b>Mysenthes LTD</b>
Device	Subject	Predicate		Reference
510(k) Number	To Be Assigned	K231325	N/A	K090926
Device Name	Theracor	Corplex P/Theracor P/Allacor P	N/A	Endoform Dermal Template
Classification	Unclassified	Unclassified	Same	Unclassified
Product Code	KGN	KGN	Same	KGN
Size/Volume	15 mm disk 1x1 cm 2x2 cm 3x5 cm	1 cc 2 cc 4 cc	Different, but does not affect safety and effectiveness	5x5 cm (2x2 in) 10x12.7 cm (4x5 in) 21.59x15.24 cm (6x8.5 in)
Nominal Sizes	Theracor is presented as a sheet.	Particles ranging from 0.1 mm to 2.0 mm	Different, same as reference. Does not affect safety and effectiveness	Presented as a sheet
Intended Use	Theracor 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	N/A
Indications for Use	Theracor is indicated for use in the management of the following wounds: <ul style="list-style-type: none"> <li>• Partial and full-thickness wounds</li> <li>• Pressure ulcers</li> <li>• Venous ulcers</li> <li>• Diabetic ulcers</li> <li>• Chronic vascular ulcers</li> <li>• Tunneled/undermined wounds</li> <li>• Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)</li> </ul>	Corplex P is indicated for use in the management of the following wounds: <ul style="list-style-type: none"> <li>• Partial and full-thickness wounds</li> <li>• Pressure ulcers</li> <li>• Venous ulcers</li> <li>• Diabetic ulcers</li> <li>• Chronic vascular ulcers</li> <li>• Tunneled/undermined wounds</li> <li>• Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)</li> </ul>	Same	Endoform is supplied sterile and is intended for single use in the treatment of the following wounds: <ul style="list-style-type: none"> <li>• Partial and full-thickness wounds</li> <li>• Pressure ulcers</li> <li>• Venous ulcers</li> <li>• Diabetic ulcers</li> <li>• Chronic vascular ulcers</li> <li>• Tunneled/undermined wounds</li> <li>• Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery,</li> </ul>

	<ul style="list-style-type: none"> <li>Trauma wounds (abrasions, lacerations, partial-thickness burns, and skin tears)</li> <li>Draining wounds</li> </ul>	<ul style="list-style-type: none"> <li>Trauma wounds (abrasions, lacerations, partial-thickness burns, and skin tears)</li> <li>Draining wounds</li> </ul>		<ul style="list-style-type: none"> <li>podiatric; wound dehiscence)</li> <li>trauma wounds (abrasions, lacerations, second-degree burns; and skin tears)</li> <li>draining wounds</li> </ul>
Configuration	Sheet	Particles	Different, same as reference. Does not affect safety and effectiveness	Sheet
Material Source	Human umbilical cord (recovered per 21 CFR 1271)	Human umbilical cord (recovered per 21 CFR 1271)	Same	Ovine collagen
Components	Collagen and associated ECM components -collagen I -collagen III -collagen V	Collagen and associated ECM components -collagen I -collagen III -collagen V	Same	N/A
Collagen (% total weight)	46% (Mean Value)	46% (Mean Value)	Same	N/A
Fibronectin	Present	Present	Same	N/A
Total Glycosaminoglycans (mg/g)	20.3 mg/g (Mean Value)	20.3 mg/g (Mean Value)	Same	N/A
Laminin	Present	Present	Same	N/A
Endotoxin (EU/device)	<20 EU/device	<20 EU/device	Same	N/A
Packaging	Dual peel-open pouch system	Glass vial with bromobutyl stopper and aluminum crimped lid, inside single peel-open pouch	Different. Differences evaluated by biocompatibility and performance testing and support SE	Single peel-pouch
Sterilization	Sterilized by electron beam irradiation	Sterilized by electron beam irradiation	Same	Ethylene oxide

Moisture Content	<15%	<15%	Same	N/A
Particle Size	Device is presented as a sheet.	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.	Different, same as reference. Does not affect safety and effectiveness	Device is presented as a sheet
Sterility Assurance Level	10 <sup>-6</sup>	10 <sup>-6</sup>	Same	10 <sup>-6</sup>
Shelf Life	One Year	One Year	Same	N/A
Prescription or OTC	Prescription	Prescription	Same	N/A
Single or Multiple Use	Single Use	Single Use	Same	N/A