June 5, 2026

BioTissue Holdings, Inc.
Lorriane Chua
Senior Director, Regulatory Affairs
7300 Corporate Center Dr., Suite 700
Miami, Florida 33126

Re: K253204
Trade/Device Name: Catalyze
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 26, 2025
Received: September 26, 2025

Dear Lorriane Chua:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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
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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)*
K253204

Device Name
Catalyze

Indications for Use *(Describe)*
Catalyze 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.

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K253204

1. SUBMITTER

BioTissue Holdings Inc.,
7300 Corporate Center Drive, Suite 700
Miami, FL 33126

Contact Person: Lorraine Chua
Position Title: Senior Director of Regulatory Affairs
Phone: 305-990-2681 ext. 839
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Date Prepared: 09/23/2025

2. DEVICE NAME

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

3. PREDICATE DEVICE:

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

4. DEVICE DESCRIPTION

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

5. INTENDED USE

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

6. INDICATIONS FOR USE

Catalyze 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 EQUIVALENCE

Catalyze is substantially equivalent to the predicate device, Corplex P/Theracor P/Allacor P (K231325) with respect to intended use, indication for use, material source (human), configuration (particles), moisture contentand sterility assurance level. Both devices are also single use prescription devices.

The primary technological differences between Catalyze and the predicate device include device size/volume, nominal particle size, material type, packaging, and sterilization method.

Performance, biocompatibility, and clinical testing conducted demonstrates that the subject device is at least as safe and effective as the predicate device, and that technological differences between them do not raise different questions of safety and effectiveness.

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

Table 1. Catalyze Substantial Equivalence

Device	Subject Device: Catalyze	Predicate Device: Corplex P/ Theracor P/Allacor P
Company	BioTissue Holdings Inc.	StimLabs, LLC
510(k) Number	K253204	K231325
Classification	Unclassified	Unclassified
Product Code	KGN	KGN
Size (Volume/ Weight)	10 mg 25 mg 50 mg 100 mg 150 mg 200 mg	1 cc 2 cc 4 cc
Nominal Particle Size	Particles ranging from 0.1 mm (100 µm) to 0.5 mm (500 µm)	Particles ranging from 0.1 mm to 2.0 mm
Indications for Use	Catalyze 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-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), • trauma wounds (abrasions, lacerations, second-degree burns and skin tears), • draining wounds	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-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), • trauma wounds (abrasions, lacerations, second-degree burns and skin tears), • draining wounds
Configuration	Particles	Particles
Material Type	Human Amniotic Membrane and Umbilical Cord (recovered per 21 CFR 1271)	Human Umbilical Cord (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
Collagen	53% (Mean Value)	46% (Mean Value)
Total Glycosaminoglycans	51.0 mg/g (Mean Value)	20.3 mg/g (Mean Value)

Device	Subject Device: Catalyze	Predicate Device: Corplex P/ Theracor P/Allacor P
Endotoxin	<20 EU/device	<20 EU/device
Packaging	Glass vial with bromobutyl stopper and aluminum crimped lid, inside single peel-open pouch	Glass vial with bromobutyl stopper and aluminum crimped lid, inside single peel-open pouch
Sterilization	Sterilized by gamma irradiation	Sterilized by electron beam irradiation
Water Content (Prior to hydration)	<15%	<15%
Sterility Assurance Level	10^{-6}	10^{-6}
Shelf Life	One Year	One Year
Prescription or OTC	Prescription	Prescription
Single or Multiple Use	Single Use	Single Use

8. PERFORMANCE TESTING

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

Catalyze Performance Testing	
Pour Test – Dry	Pass
Pour Test – Wet	Pass
Solution Compatibility Test	Pass
Evaporation Test	Pass
Absorption Test	Pass
Appearance	Pass
Collagen Content- Quantitative	Pass
Total Glycosaminoglycans- Quantitative	Pass
ECM Characterization	Pass

9. BIOCOMPATIBILITY TESTING

Catalyze 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 10993-23: 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
- Packaging System Cytotoxicity: ISO 10993-5:2009- Tests for in vitro cytotoxicity
- Viral Inactivation Study per ISO 22442-3

10. CLINICAL TESTING

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

- Human Repeat Insult Patch Test
- Skin Prick Test

11. CONCLUSION

Catalyze has the same intended use and substantially similar technological characteristics to the predicate device. The performance, biocompatibility including human clinical testing that have been performed demonstrates that the subject device is at least as safe and effective as the predicate device, and that technological differences between them do not raise different questions of safety and effectiveness.