botiss biomaterials GmbH
Elena Pies
Manager Regulatory Affairs
Hauptstrasse 28
Zossen, 15806
GERMANY

December 12, 2025

Re: K242817
Trade/Device Name: Jason membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPL
Dated: March 28, 2025
Received: November 12, 2025

Dear Elena Pies:

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*
K242817

Device Name
Jason membrane

Indications for Use *(Describe)*
Jason membrane alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) is indicated for immediate or delayed guided tissue and bone regeneration.
- in case of surgical bone defects and bone wall defects
- in the context of sinus floor augmentation and for support of the Schneiderian membrane
- in the context of maxillary ridge augmentation
- in the context of maxillary ridge reconstruction for prosthetic treatment
- in the context of a treatment of fenestration defects
- in case of periodontal bone defects (one to three-wall defects, class I and II furcation defects)
- in case of dehiscence defects
- after apicoectomy, cystectomy, resection of retained teeth and resection of other bone lesions
- in extraction sockets after tooth extractions
- in case of immediate or delayed augmentation around implants in extraction sockets

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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510(k) Summary according to 21 CFR 807.92

Submitter: botiss biomaterials GmbH
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Registration No.: 3014206569 Owner/Operator No.: 10058419
Primary Contact: Katja Pratsch, Managing Director Quality Management & Regulatory Affairs
Secondary Contact: Elena Pies, Manager Regulatory Affairs
Date Prepared: December 12, 2025

Device:
Device name: Jason® membrane
510(k) Number: K242817
Common name: Barrier, animal source, intraoral
Classification Panel: Dental Devices
Classification Name: NPL (Class 2) – Bone grafting material (21 CFR 872.3930)
Predicate Device: Straumann® Jason® membrane - K173562

Device Description: Jason® membrane is a completely resorbable collagen membrane used in maxillofacial surgery, implantology, periodontology, oral surgery and endodontology as a barrier membrane to support guided tissue regeneration (GTR) and guided bone regeneration (GBR), for covering implants and for periodontal tissue regeneration. Jason® membrane is produced from porcine pericardium in a standardized, controlled purification process. When dry Jason® membrane is a white collagen matrix with a very dense fiber structure. It possesses sufficient rigidity and stability for a broad variety of intended uses. Jason® membrane possesses a physiological neutral pH-value. Jason® membrane typically resorbs within 12 weeks after implantation. The Jason® membrane is intended to be used in adults only.

Jason® membrane is offered in three sizes and two different brands as shown below.

Article No.	Size	Content
BS-681520	15 × 20 mm	1 membrane
BS-682030	20 × 30 mm	1 membrane
BS-683040	30 × 40 mm	1 membrane

510(k) Summary according to 21 CFR 807.92

Picture of Device

Indications for Use:

Jason® membrane alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) is indicated for immediate or delayed guided tissue and bone regeneration.

- in case of surgical bone defects and bone wall defects
- in the context of sinus floor augmentation and for support of the Schneiderian membrane
- in the context of maxillary ridge augmentation
- in the context of maxillary ridge reconstruction for prosthetic treatment
- in the context of a treatment of fenestration defects
- in case of periodontal bone defects (one to three-wall defects, class I and II furcation defects)
- in case of dehiscence defects
- after apicoectomy, cystectomy, resection of retained teeth and resection of other bone lesions
- in extraction sockets after tooth extractions
- in case of immediate or delayed augmentation around implants in extraction sockets

Materials:

Jason® membrane is manufactured from the pericardium of domestic swine. The chemical content of 10 cm^2 Jason® membrane is:

- 30 - 40 mg collagen type I
- 5 - 10 mg purified water
- Up to 10% salts as sodium phosphate

510(k) Summary according to 21 CFR 807.92

Comparison of Technological Characteristics with the Predicate Device:

The technological characteristics of the subject device Jason® membrane are substantially equivalent to the predicate device. The intended use of the subject device is identical to the predicate device.
A comparison of the relevant technological characteristics between the subject and the predicate device is provided in Table 1.

Table 1 - Summary of Technological Characteristics

Feature	Subject Device Jason® membrane	Predicate Device Jason® membrane	Equivalence Discussion
Indications for Use	Jason membrane alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) is indicated for immediate or delayed guided tissue and bone regeneration. • in case of surgical bone defects and bone wall defects • in the context of sinus floor augmentation and for support of the Schneiderian membrane • in the context of maxillary ridge augmentation • in the context of maxillary ridge reconstruction for prosthetic treatment • in the context of a treatment of fenestration defects • in case of periodontal bone defects (one to three-wall defects, class I and II furcation defects) • in case of dehiscence defects • after apicoectomy, cystectomy, resection of retained teeth and resection of other bone lesions • in extraction sockets after tooth extractions • in case of immediate or delayed augmentation around implants in extraction sockets	Jason membrane alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) is indicated for immediate or delayed guided tissue and bone regeneration. • in case of surgical bone defects and bone wall defects • in the context of sinus floor augmentation and for support of the Schneiderian membrane • in the context of maxillary ridge augmentation • in the context of maxillary ridge reconstruction for prosthetic treatment • in the context of a treatment of fenestration defects • in case of periodontal bone defects (one to three-wall defects, class I and II furcation defects) • in case of dehiscence defects • after apicoectomy, cystectomy, resection of retained teeth and resection of other bone lesions • in extraction sockets after tooth extractions • in case of immediate or delayed augmentation around implants in extraction sockets	**Identical**
Mode of Action	Jason functions as a barrier when applied between bone graft material and soft tissue. The membrane serves as a bioresorbable scaffold that is eventually remodeled, resorbed, and replaced by host tissue.	Jason functions as a barrier when applied between bone graft material and soft tissue. The membrane serves as a bioresorbable scaffold that is eventually remodeled, resorbed, and replaced by host tissue.	**Identical**

510(k) Summary according to 21 CFR 807.92

Feature	Subject Device Jason® membrane	Predicate Device Jason® membrane	Equivalence Discussion
Operating Principles	Cell-Occlusive Implantable Resorbable Biocompatible	Cell-Occlusive Implantable Resorbable Biocompatible	**Identical**
Material	Intact purified collagen tissue	Intact purified collagen tissue	**Identical**
Collagen Source	Porcine pericardium	Porcine pericardium	**Identical**
Form	Membrane	Membrane	**Identical**
Appearance	White to off-white	White to off-white	**Identical**
Sizes	• 15 x 20 mm • 20 x 30 mm • 30 x 40 mm	• 15 x 20 mm • 20 x 30 mm • 30 x 40 mm	**Identical**
Resorption Time	Substantially resorbed by 12 Weeks	Substantially resorbed by 12 Weeks	**Identical**
Sterilization Method	Ethylene Oxide (EO)	Ethylene Oxide (EO)	**Identical**
Shelf Life	3 years	3 years	**Identical**
Singe Use/ Reuse	Single use only	Single use only	**Identical**
Packaging	Supplied in a double pouch pack.	Supplied in a double pouch pack.	**Identical**
Biological characteristics	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	**Biologically equivalent**

Performance Data:

Performance testing was performed as per the design control system.

- Validation of shelf life per ASTM F1980, ISO 11607-1 and ISO 11607-2
- Validation of transport packaging per ASTM D7386
- Validation of sterilization process per ISO 11135
- Biocompatibility testing per ISO 10993-1, -5, -17 and -18
- Viral Inactivation per ISO 22442-3
- Performance Testing per ASTM F2212

The chemical characterization testing and subsequent toxicological risk assessment outlined in ISO 10993-17 / -18 have demonstrated a negligible risk of systemic toxicity.
Cytotoxicity testing as outlined in ISO 10993-5 demonstrated the subject device is non-cytotoxic.
Biocompatibility testing satisfying the requirements outlined in ISO 10993-1 demonstrates that the subject device is substantially equivalent to the predicate device and biocompatible for its intended use.

No human clinical studies were conducted.

510(k) Summary according to 21 CFR 807.92

Substantial Equivalence:

The subject device Jason® membrane is substantially equivalent to the predicate device when evaluating intended use and technological characteristics.

- The subject device has the identical intended use and indications for use as the predicate device.
- The subject device and predicate device are substantially equivalent in materials, principle of operation, sterilization, etc.
- Performance testing and biocompatibility testing demonstrates that the subject device is as safe and effective as the predicate device and does not raise new or different questions of safety and effectiveness compared to the predicate device.

Conclusions:

The subject device Jason® membrane met the established safety and performance characteristics. Performance testing demonstrates Jason® membrane is as safe and effective as the predicate device and will perform as intended.

The subject device Jason® membrane with respect to the design, chemical characterization and biological characteristics is substantially equivalent to the predicate device.

The subject device has the same intended use and fundamental scientific technology as the predicate device. The subject device is substantially equivalent to the predicate device cleared under K173562.