September 3, 2020

B. Bruan Surgical, SA
% Robin Fatzinger
Principle Consultant
Qreg Consulting, LLC
2192 Martin Drive
Gilbertsville, Pennsylvania 19525

Re: K192452
Trade/Device Name: Lyograft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: July 31, 2020
Received: August 3, 2020

Dear Robin Fatzinger:

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 (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 located 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.

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

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

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192452

Device Name
Lyograft

Indications for Use *(Describe)*
Lyograft® is intended for implantation to repair, reinforce and/or supplement soft tissue.

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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"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."

5. 510(k) Summary as Required by 21 CFR 807.92(c).

I. SUBMITTER

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Contact Person: Pau Turon Dols, Ph.D
Director of R&D, Regulatory, & Quality

Date Prepared: 06 September 2019

II. DEVICE

Name of Device: Lyograft®

Common or Usual Name: Mesh, Surgical

Classification Name: Surgical Mesh (21 CFR 878.3300)

Regulatory Class: II

Product Code: FTM

III. PREDICATE DEVICE

TUTOMESH®, K091142 *(B. Braun Surgical, S.A. is not aware of this predicate device being subject to a design-related recall.)*

Lyoplant (K970851) and Lyoplant Onlay (K122791) will be used as reference devices to support product safety. Lyoplant and Lyoplant Onlay are dura substitutes (GXQ) which are manufactured from the identical bovine pericardium material by B. Braun Melsungen AG (Carl-Braun-Straße 1 - 34212 Melsungen, Germany), the parent company of B. Braun Surgical, S.A.

IV. DEVICE DESCRIPTION

Lyograft is a biological surgical mesh comprised of pure collagen made of bovine pericardium. It is a single layered membrane of connective tissue with the collagen fibers running in three dimensions. Lyophilization causes the formation of a mesh, free of non-collagenous components, with a loose fibrous structure and large communicating pores. Lyograft is a long-term implant that will be incorporated into the patient's tissue over time.

Lyograft is supplied in various sizes ranging from 8x14cm to 20x30cm. It is provided sterile within a double blister package and is for single use. Lyograft is rehydrated in a physiological saline solution and

cut to size using aseptic technique prior to use. It is recommended to suture Lyograft in place using nonabsorbable sutures.

V. INDICATIONS FOR USE

Lyograft® is intended for implantation to repair, reinforce and/or supplement soft tissue.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	TUTOMESH® - *Predicate*	**Lyograft® - *Subject Device***
510(k) Number	K091142	TBD
Device Class	II	II
Product Code	FTM	FTM
Panel	878.3300 General & Plastic Surgery	878.3300 General & Plastic Surgery
Intended Use	Implanted to reinforce soft tissue or bone where weakness exists.	Implanted to reinforce soft tissue where weakness exists.
Indications for Use	This device is intended for implantation to repair, reinforce and/or supplement soft tissue.	Lyograft® is intended for implantation to repair, reinforce and/or supplement soft tissue.
Material Source	Bovine Pericardium	Bovine Pericardium
Material Type	Acellular, non-crosslinked, 3-dimensional Collagen Matrix	Acellular, non-crosslinked, 3-dimensional Collagen Matrix
Resorbable	Yes	Yes
Shape(s)	Oval	Rectangular
Size(s)	10 x 16cm & 13 x 22cm	8 x 14cm to 20 x 30cm
How Supplied	Double Blister Package	Double Blister Package
Sterilization Method	Tutoplast® Tissue Sterilization Process and Gamma Irradiation	EtO
Reusable	Single Use	Single Use

VII. PERFORMANCE DATA

FDA Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (March 2, 1999) was considered in determining the requirements for demonstrating substantial equivalence to the predicate device. The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for Lyograft was conducted in accordance with ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. Lyograft is considered a long term (>30 days) implant which comes in contact with tissue. The following tests have been considered per the standard:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity
- Material Mediated Pyrogenicity
- Subchronic Toxicity
- Chronic Toxicity
- Hemolysis
- Genotoxicity
- Implantation

Performance Testing – Bench

The following tests were conducted on both the subject and predicate devices to evaluate the performance characteristics and collagen purity:

- Tensile Strength
- Burst Strength
- Density Weight/Area
- DSC Analysis
- FTIR Analysis
- Acetic Acid Test
- Hydroxyproline Test
- Water Content

Performance Testing – Animal

An animal study comparing the performance of Lyograft and Tutomesh for tissue reinforcement in the abdominal wall and tissue integration in a rabbit model was conducted. Sixteen (16) female New Zealand White rabbits were assigned to the following groups: Four (4) rabbits implanted with Lyograft for 12-week explantation and four (4) rabbits implanted with Tutomesh for 12-week explantation; four (4) rabbits implanted with Lyograft for 24-week explantation and four (4) rabbits implanted with Tutomesh for 24-week explantation. The test (Lyograft) and reference (Tutomesh) samples were cut to a defined size and sutured to the traumatized abdominal wall per standard procedure.

The test and reference surgical sites were macroscopically examined after 12 and 24 post-operative weeks subsequently explanted for further histological examination. The results for Lyograft and Tutomesh at both the 12 and 24-week time points showed similar local tissue reaction and tissue integration.

VIII. CONCLUSIONS

The subject device, Lyograft, and the predicate device, Tutomesh, are both biological surgical mesh made from bovine pericardium and utilize the same technological characteristics and principles to reinforce soft tissue where weakness exists. The devices have the same biocompatibility safety profile and similar performance as demonstrated in bench and animal testing described above. Any minor differences in performance test results do not raise new issues of safety. Therefore, based on these similarities, Lyograft is considered substantially equivalent to Tutomesh.