



Food and Drug Administration
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January 8, 2016

Fibralign Corporation
c/o Mr. Ronald S. Warren
Experien Group, LLC
755 N. Mathilda Avenue, Suite 100
Sunnyvale, CA 94085

Re: K151083
Trade/Device Name: BioBridge Collagen Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY
Dated: December 7, 2015
Received: December 8, 2015

Dear Mr. Warren:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151083

Device Name
BioBridge™ Collagen Matrix

Indications for Use (Describe)

The BioBridge™ Collagen Matrix is intended to reinforce soft tissue where weakness and deficiencies exist, specifically, for reinforcement of soft tissue repaired by sutures or suture anchors in tendon repair, including small tendons, ligaments, and general surgical procedures for tissue repair where weakness exists, including muscle flap reinforcement.

BioBridge is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

510(k) Notification K151083

I. GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: January 8, 2016

II. DEVICE INFORMATION [807.92(a)(2)]

Trade/Proprietary Name:

BioBridge™ Collagen Matrix

Generic/Common Name:

Surgical mesh

Classification Name:

Mesh, Surgical, Collagen, Plastic and Reconstructive Surgery

Regulatory Classification:

Class II per 21 CFR§878.3300

Product Code:

OWY

510(k) SUMMARY

III. PREDICATE DEVICES [807.92(a)(3)]

- **Primary predicate device:** TRELIS™ Collagen Ribbon – Wright Medical Technology, Inc. (K131143; K120019)
- **Additional predicate device:** HP Tissue Matrix (HPTM)– LifeCell Corporation (K142326; K08)
- **Reference device:** Ossix™ Plus – ColBar LifeSciences Ltd. (K053260)

The ColBar Ossix Plus device is included as a reference device as it is sourced from Datum Dental, the same supplier of collagen used in BioBridge, and is a similar device made of purified pepsin-treated Collagen Type I.

IV. DEVICE DESCRIPTION [807.92(a)(4)]

BioBridge is a sterile implantable biocompatible and biodegradable surgical mesh ribbon comprised of highly purified porcine collagen that is designed to provide mechanical support for weaknesses and deficiencies in soft tissue. The collapsed ribbon structure contains multiple folds of a thin membrane with aligned collagen fibrils in the same lengthwise direction. This structure provides mechanical properties that contribute to strong tensile strength, that which provides support to weaknesses and deficiencies in soft tissue and aids in bridging a connection between two healthy soft tissues.

BioBridge is fabricated using a proprietary manufacturing process that produces a narrow and very thin ribbon-like membrane comprised of collagen fibrils, creating a multi-luminal structure that provides mechanical properties for support of soft tissue repair. This approach presents the opportunity to enable the use of highly purified, pepsin treated collagen, in a defined structure that has mechanical properties similar to those of the predicates. The smaller ribbon-like form factor gives the surgeon greater flexibility to tailor their procedures compared to the predicates without changing the intended use. One or more BioBridge devices can be implanted depending on the surgeon's discretion, including arrangement of the individual devices in bundles or braided together by the physician, to better address a specific patient need. It is particularly well suited, for example, in supporting repair of small tendons and ligaments. Fibralign sources the highly purified porcine-derived Type I collagen from an FDA-registered and ISO-qualified supplier. Fibralign employs a proprietary manufacturing process that takes highly purified porcine-derived Type I collagen and produces narrow, ribbon-like membranes comprised of highly aligned collagen fibrils that provides mechanical strength for use in supporting soft tissue. A chemical crosslinking agent is used during the manufacturing process to promote the crosslinking of the collagen but the crosslinker itself is not added to nor bound to the collagen matrix. The crosslinker residuals are water soluble and are removed by product rinsing at the end of the production process. The final product is packaged into individual storage containers and then sealed within an outer tray and terminally sterilized.

V. INDICATIONS FOR USE [807.92(a)(5)]

The Indication for Use statement for the BioBridge™ Collagen Matrix is as follows:

510(k) SUMMARY

The BioBridge™ Collagen Matrix is intended to reinforce soft tissue where weakness and deficiencies exist, specifically, for reinforcement of soft tissue repaired by sutures or suture anchors in tendon repair, including small tendons, ligaments, and general surgical procedures for tissue repair where weakness exists, including muscle flap reinforcement.

BioBridge is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair.

The Indications for Use statement for the BioBridge are semantically similar to the predicate device; however, the differences are not critical to the intended surgical use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended surgical use for the reinforcement and repair of soft tissue where weakness exists.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

The primary predicate device TRELIS received 510(k) clearance (K131143; K120019) as a narrow, ribbon-like version of its predicate, the WMT Dermal Matrix (K073219). The new dimensions of TRELIS allowed for new surgical techniques (i.e. support of soft tissue in orthopedic applications) as compared to its predicate (Wright Dermal Matrix) but did not change the intended use of the device from its predicate. Similarly, the proposed BioBridge device is a thinner collagen ribbon than the primary predicate device, which provides greater flexibility to the surgeon and allows for further expansion of the potential surgical techniques for soft tissue repair, but does not change the intended use of the device as compared to this predicate.

In addition, BioBridge is comparable with respect to intended use to the LifeCell HPTM device (K142326; K082176) which is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The HPTM device is a surgical mesh derived from porcine dermis and the implant is intended for reinforcement of soft tissue in plastic and reconstructive surgery.

VII. PERFORMANCE DATA [807.92(b)]

All necessary bench and non-clinical testing were conducted on the BioBridge to support a determination of substantial equivalence to the predicate device.

[807.92(b)(1)]

Nonclinical Testing Summary:

The nonclinical bench testing and in vivo testing included:

- Dry Tensile Pull Test
- Wet Tensile Pull Test

510(k) SUMMARY

- Suture Pull Test
- Surgical Knot Tensile Test
- Length and Diameter measurements
- Characterization of collagen, water, and crosslinking
- Enzymatic degradation rate
- Biocompatibility testing
- In vivo studies including a rabbit tendon repair model which evaluated the degradation rate as well as the mechanical strength of the repair over time

Biocompatibility testing was completed on the finished BioBridge device and on the porcine collagen raw material per ISO 10993 requirements for a permanent implant.

In addition to the nonclinical bench testing, the performance of the BioBridge device was supported by animal studies. A porcine model and rabbit tendon model were employed to support the intended use of the device.

The collective results of the nonclinical testing demonstrate that the materials chosen and the design of the BioBridge meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench and animal testing demonstrates that BioBridge does not raise new questions of safety or effectiveness for soft tissue reconstruction when compared to the predicate devices.

[807.92(b)(2)]

Clinical Testing Summary:

This section is not applicable as the 510(k) clearance of this device was not supported by clinical testing.

[807.92(b)(3)]

The collective results of the nonclinical testing demonstrate that the BioBridge materials and design meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that BioBridge does not raise new questions of safety or effectiveness for surgical use for the reinforcement and repair of soft tissue where weakness exists when compared to the predicate devices.

VIII. CONCLUSIONS

The BioBridge device subject to this 510(k) is substantially equivalent to the predicate devices, namely the Wright Medical Technology, Inc. TRELIS™ Collagen Ribbon (K131143; K120019), as well as the LifeCell HPTM device (K142326).