July 14, 2021

Geistlich Pharma AG
% Joshua Crist, MSE
Senior Consultant
Biologics Consulting Group, Inc.
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K203496
Trade/Device Name: Nexo-Gide™ Bilayer Collagen Membrane
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, OWW
Dated: June 14, 2021
Received: June 15, 2021

Dear Joshua Crist:

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,

Laura C. Rose -S

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K203496

Device Name
Nexo-Gide™ Bilayer Collagen Membrane

Indications for Use *(Describe)*
The Nexo-Gide™ Bilayer Collagen Membrane is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon 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.

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510(K) SUMMARY

1. SUBMITTER

Submitter:	Geistlich Pharma AG Bahnhofstrasse 40 CH-6110 Wolhusen Switzerland Phone: +41 41 492 67 64 Fax: +41 41 492 55 40
Contact Person:	Marco Steiner Director Regulatory Affairs Geistlich Pharma AG Phone: +41 41 492 67 64 Marco.Steiner@geistlich.ch
Submission Correspondent:	Joshua Crist Senior Consultant Biologics Consulting Group, Inc. 1555 King Street, Suite 300 Alexandria, VA 22314 Phone: 216-387-0199 jcrist@biologicsconsulting.com
Date Prepared:	October 15, 2020

2. DEVICE

Name of Device:	Nexo-Gide™ Bilayer Collagen Membrane
Common or Usual Name:	Surgical Mesh
Classification Name:	878.3300 - Surgical Mesh
Regulatory Class:	Class II
Product Code:	OWW, FTM

3. PREDICATE DEVICE

Predicate Device Name:	Tendon Wrap Tendon Protector
Manufacturer:	Integra LifeSciences
510(k) Number:	K053655
Reference Devices:	K192042 Bio-Gide, Geistlich Pharma AG

4. DEVICE DESCRIPTION

The Geistlich Nexo-Gide™ device, manufactured by Geistlich Pharma AG, is a resorbable collagen membrane of porcine origin, consisting of a compact smooth structure and of a porous structure that serves as an interface between the tendon and the surrounding tissues. Nexo-Gide™ Bilayer Collagen Membrane will be used as a tendon protector sheet that provides a non-constricting, protective encasement for injured tendon, in the same manner as other tendon cover products like the predicate device TenoGlide (K053655, Integra Life Science).

The Nexo-Gide membrane is made of collagen type I and III without further cross-linking or chemical additives and is sterilized by gamma irradiation. The available sizes are 20x30mm, 30x40mm and 40x50 mm.

5. INDICATION FOR USE

The indications for use for the Nexo-Gide™ Bilayer Collagen Membrane are as follows:

> *The Nexo-Gide™ Bilayer Collagen Membrane is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.*

The indications for use are identical to the predicate device.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Discussion of Similarities

Both devices are collagen membranes used to protect and manage tendon injuries where there is no substantial loss of tendon tissues. Both devices are used in the same manner. Both devices are of comparable thickness and pore size, and have similar mechanical properties such as suture pull-out force, stiffness, and tensile strength. Both devices are resorbable and biocompatible in accordance with ISO 10993-1 and FDA guidance. Both devices are sterile, single-use devices. The technological features and use of these products are overall very similar, with minor differences in the tissue sourcing and processing.

Discussion of Differences

The proposed device differs from the predicate in its tissue source and composition. The predicate device is sourced from bovine tendon tissue and is composed of primarily cross-linked type I collagen. The proposed Geistlich Nexo-Gide device, however, is sourced from porcine tissue and is composed of primarily Type I and Type III collagen. The proposed device also has a bilayer structure intended to provide a tendon-facing and outward-facing surfaces suited for the intended use of protection and management of tendon injuries. These similarities and differences are summarized in the device comparison table below.

Device Comparison Table:

	Proposed Device	**Predicate Device**[1] K053655	**Bio-Gide K192042 (Material Reference Device)**
510(k) Number	TBD	K053655	K192042
Applicant	Geistlich Pharma AG	Integra LifeSciences	Geistlich Pharma AG
Device Name	Nexo-Gide™ Bilayer Collagen Membrane	Tendon Wrap Tendon Protector (TenoGlide)	Bio-Gide
Classification Regulation	878.3300 - Surgical Mesh	878.3300 - Surgical Mesh	872.3930 - Bone grafting material
Product Code	FTM – Surgical Mesh OWW - Mesh, Surgical, Absorbable, Orthopedics, Reinforcement Of Tendon	FTM – Surgical Mesh	NPL - Bone grafting material.

[1] Descriptive information on the predicate was obtained from the 510(k) summary and available FOI records of K053655

	Proposed Device	**Predicate Device**[1] K053655	**Bio-Gide** **K192042 (Material Reference Device)**
Indications for Use	The Nexo-Gide™ Bilayer Collagen Membrane is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.	Tendon Wrap Tendon Protector is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.	Augmentation around implants placed in immediate extraction sockets; augmentation around implants placed in delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects after root resection, cystectomy, removal of retained teeth; guided bone regeneration in dehiscence defects; and guided tissue regeneration procedures in periodontal defects.
Target Population	Patients with injuries to tendons of the extremities	Patients with injuries to tendons of the extremities	Bone grafting patients
Physical Appearance	Almost white collagen membrane consisting of a collagen network of multiple layers	Beige collagen membrane consisting of a collagen network of multiple layers	Almost white collagen membrane consisting of a collagen network of multiple layers
Handling	Product is soft and conformable	Product is soft and conformable	Product is soft and conformable
Thickness	≥ 0.2 mm	≥ 0.2 mm	≥ 0.2 mm
Porosity	Pores from 1 – 120 µm	Pores from 1 – 120 µm	Pores from 1 – 120 µm
Tensile Strength (maximal stress)	≥0.06 MPa	≥0.06 MPa	≥0.06 MPa
Stiffness (elasticity)	≤65 MPa	≤65 MPa	≤65 MPa
Suture Pull out forces	Suture pull out force: ≥ 0.04 N, allows suturing	Suture pull out force: ≥ 0.04 N, allows suturing	Suture pull out force: ≥ 0.04 N, allows suturing
Integrity	Device has proven integrity under simulated physiological conditions	Device has proven integrity under simulated physiological conditions	Device has proven integrity under simulated physiological conditions

	Proposed Device	**Predicate Device[1]** K053655	**Bio-Gide** **K192042 (Material Reference Device)**
Materials of Composition			
Raw Material	porcine collagen	Type I Collagen from bovine flexor tendon	porcine collagen
Major Components	collagen type I and III without further cross-linking or chemical additives	Crosslinked type I collagen and glycosaminoglycan (GAG)	collagen type I and III without further cross-linking or chemical additives
Other Characteristics			
Source of raw material	sourced from pigs (Sus scrofa domestica)	bovine	sourced from pigs (*Sus scrofa domestica*)
Packaging	Sterile double blister packaging. Conforms to ISO 11607, Parts 1 and 2.	"double peel packages"	Sterile double blister packaging. Conforms to ISO 11607, Parts 1 and 2.
Manufacture / Packaging location	Geistlich Pharma AG, Wolhusen, Switzerland Registration Number: 9614442	Integra LifeSciences, Plainsboro, NJ08536 USA Establishment Registration Number 1121308	Geistlich Pharma AG, Wolhusen, Switzerland Registration Number: 9614442
Sterility	Gamma irradiation SAL 10^{-6}; Sterile, for single use only	"sterile, single use"	Gamma irradiation SAL 10^{-6} Sterile, for single use only
Principles of Operation			
Principles of Operation	Single use, biocompatible, implantable and resorbable collagen sheet which serves as a protective encasement for injured tendons	Single use, biocompatible, implantable and resorbable collagen sheet which serves as a protective encasement for injured tendons	Single use, biocompatible, implantable and resorbable collagen membrane which serves as a dental barrier membrane
Bicompatible	Biocompatibility assessment conducted according to ISO 10993-1 and confirmed biocompatible	Biocompatibility assessment conducted according to ISO 10993-1	Biocompatibility assessment conducted according to ISO 10993-1 and confirmed biocompatible

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

According to the requirements of FDA's guidance on the Use of International Standard ISO 10993, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, Geistlich Nexo-Gide is categorized as an implant in contact with tissue and bone for a permanent duration (> 30 days). Geistlich Nexo-Gide is identical in raw material source, formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents), when compared to legally marketed predicates with the biocompatibility contact/duration classification (Geistlich Bio-Gide K192042 and K050446).

Additionally, however, a Chicken Tendon Flexor study was conducted which provided safety and effectiveness information, including biocompatibility insights for the intended anatomical use location, that also support biocompatibility and substantial equivalence to the predicate.

Geistlich Nexo-Gide meets the pyrogen limits specification. Bacterial endotoxins are determined by the Limulus Amoebocyte Lysate (LAL) test according to USP <85> Bacterial Endotoxins, gel-clot technique and must not exceed 20.0 USP EU per device.

Electrical Safety and electromagnetic compatibility (EMC)

Not applicable. The subject device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software Verification and Validation Testing

Not Applicable. The subject device contains no software.

Bench Testing

Bench testing was conducted versus the predicate to support substantial equivalence, including the following tests:

- Physical Appearance
- Thickness
- Porosity
- Tensile Strength and Stiffness
- Suture Pull out forces
- Integrity

All tests passed the predetermined acceptance criteria, demonstrating substantial equivalence to the predicate.

Animal Study

The Geistlich Nexo-Gide® device has been studied in various different animal models involving tendon and other relevant anatomical locations.

Nexo-Gide, demonstrated similar safety and effectiveness when compared to the control article, TenoGlide, in a chicken flexor tendon repair model. Histologically, Nexo-Gide was considered to have minimal or no reaction compared to the TenoGlide predicate device. The application of Nexo-Gide reduced WOF when compared to the surgical control and, statistically, was non-inferior compared to the predicate device. Tendon healing and adherence formation was similar between Nexo-Gide and the predicate TenoGlide, and there were no adverse events differentiating the two groups. The study therefore met all acceptance criteria and

Additionally, Nexo-Gide was compared to the predicate device in a rat achilles tendon study to assess the degradation profile and to evaluate local tissue effects. Nexo-Gide had similar tissue and inflammation responses compared to the control article with minimal or no reaction. Nexo-Gide demonstrated similar performance under the conditions of the study.

Further, previously conducted animal studies had been leveraged to demonstrate product safety and performance. Local tissue reactions, product degradation and systemic toxicity with the implant was assessed in these studies.

Any differences in technology for the Geistlich Nexo-Gide do not negatively impact safety and effectiveness of the device. This testing therefore demonstrates that Geistlich Nexo-Gide is substantially equivalent to the predicate in its ability to protect and manage tendon injuries in which there has been no substantial loss of tendon tissue.

Clinical Study

Not applicable – clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSIONS

The Geistlich Nexo-Gide device has the same intended use and few technological differences when compared to the predicate TenoGlide. The primary difference is Geistlich Nexo-Gide uses a different tissue source which may impact biocompatibility and mechanical properties. The biocompatibility of the device is supported by identical composition to previously marketed devices, and bench testing demonstrates any differences in material composition do not impact safety and effectiveness of mechanical properties. Finally, a chicken tendon flexor model demonstrates that Geistlich Nexo-Gide is substantially equivalent to the predicate in its ability to protect and manage tendon injuries in which there has been no substantial loss of tendon tissue. Taken together, Geistlich Nexo-Gide has the same intended use as the predicate and all concerns regarding differences in technology have been addressed through bench and animal testing, and therefore Geistlich Nexo-Gide can be considered substantially equivalent to the predicate.