May 26, 2023

International Life Sciences
Tiffini Wittwer
Vice President Quality and Regulatory Affairs
2150 Northwest Parkway SE Suite G
Marietta, Georgia 30076

Re: K230316
Trade/Device Name: FlexBand®; FlexPatch®; FlexBand® Plus
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: QWJ, FTL, OWW
Dated: April 26, 2023
Received: April 27, 2023

Dear Tiffini Wittwer:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230316

Device Name
FlexBand®, FlexPatch®, and FlexBand® Plus

Indications for Use *(Describe)*
FlexBand®, FlexPatch®, and FlexBand® Plus are intended for use in surgical procedures for reinforcement of soft tissue where weakness exists.
FlexBand®, FlexPatch®, and FlexBand® Plus are also intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during tendon and ligament repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendons, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments.
FlexBand®, FlexPatch®, and FlexBand® Plus is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, quadriceps tendons, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments. Sutures, used to repair the tear, and sutures or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the tendon repair. The products reinforce soft tissue and provides a degradable scaffold that is incorporated into the patient's own 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.

510(K) Summary: K230316

FlexBand®/ FlexPatch® / FlexBand® Plus

I. Submitter Information

Submitter:	International Life Sciences (dba Artelon)
Address:	2150 Northwest Pkwy SE Suite G Marietta GA 30076
Telephone:	+1 (800) 610-3446
Contact:	Tiffini Wittwer, MPH
Date Prepared:	May 23, 2023

II. Device Information

Trade Name(s):	FlexBand® / FlexPatch® / FlexBand® Plus
Common Name:	Surgical Mesh
Classification:	Class II
Regulation:	21 CFR 878.3300
Classification Name:	Mesh, Surgical, Absorbable, Orthopedics, Reinforcement of Ligament
Classification Panel:	Orthopedic
Product Codes:	QWJ, OWW, FTL

III. Predicate Device Information

The FlexBand® / FlexPatch® / FlexBand® Plus devices described in this submission are substantially equivalent to the following predicate devices:

The FlexBand® / FlexPatch® / FlexBand® Plus (K192112)

BioBridge™ Collagen Matrix (K151083)

IV. Device Description

The FlexBand® / FlexPatch® / FlexBand® Plus products are knitted mesh made from ARTELON® fibers. ARTELON® fiber is made of degradable polycaprolactone-based polyurethane urea. The construction permits the mesh to be cut into any desired shape or size without unraveling. FlexBand® Plus devices have suture attached to each end of the knitted mesh strip. The pre-loaded suture is intended to aid in usability in the operating room. The devices are supplied sterile, one product per package in double layer peel pouch packaging.

V. Indication for Use

FlexBand®, FlexPatch®, and FlexBand Plus® are intended for use in surgical procedures for reinforcement of soft tissue where weakness exists.

FlexBand®, FlexPatch®, and FlexBand Plus® are also intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during tendon and ligament repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendons, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments.

FlexBand®, FlexPatch®, and FlexBand Plus® is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, quadriceps tendons, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments. Sutures, used to repair the tear, and sutures or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the tendon repair. The products reinforce soft tissue and provides a degradable scaffold that is incorporated into the patient's own tissue.

VI. Comparison of Technological Characteristics With the Predicate Devices

FlexBand®, FlexPatch®, and FlexBand Plus® devices have the same principles of operation as the predicate devices (K192112 and K151083). They are all implants intended for the reinforcement of soft tissues that are repaired by suture or other fixation devices. The devices are used in various surgical procedures where soft tissue reinforcement is needed.

FlexBand®, FlexPatch®, and FlexBand Plus® products are similar to the BioBridge predicate (K151083) in the following ways:

- Intended use, to share load placed on the primary repair and provide structural scaffold for torn or damaged soft tissue;
- Indication for Use
- Radiation sterilization (E-Beam method, minimum 25 kGy)
- Biodegradable
- May be cut to size to meet surgeons' preference

There have been no changes to the FlexBand®, FlexPatch®, and FlexBand Plus® products since the prior 510(k) clearance. Therefore, FlexBand®, FlexPatch®, and FlexBand Plus® products are the same as the FlexBand®, FlexPatch®, and FlexBand Plus® predicate (K192112) in the following ways:

- Material
- Knit patterns and design.
- Product sizes and packaging configuration

VII. Performance Data

Mechanical testing

- Suture Retention Testing
- Tensile Strength Testing

The tests listed above provide objective evidence that the FlexBand®, FlexPatch®, and FlexBand Plus® devices provide adequate mechanical properties for use in ligament soft tissue reinforcement. The performance data risk / benefit analysis concluded that the differences do not affect the safety and effectiveness of the FlexBand®, FlexPatch®, and FlexBand Plus® device in relation to the predicate.

Routine endotoxin (LAL) testing is performed on each production lot to monitor endotoxin levels.

Clinical Literature

Clinical literature was provided on the subject device involving ligament reinforcement procedures. The reviewed literature shows the device is effective when used in the proposed ligament indication.

VIII. Conclusion

Based on the above information the FlexBand®, FlexPatch®, and FlexBand Plus® products are substantially equivalent to the soft tissue reinforcement predicate devices:

The FlexBand® / FlexPatch® / FlexBand® Plus (K192112)

BioBridge™ Collagen Matrix (K151083)