September 27, 2019

International Life Sciences
Tiffini Wittwer
Regulatory Affairs
2252 Northwest Parkway SE
Marietta, Georgia 30067

Re: K192112
Trade/Device Name: FlexBand Plus
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: August 27, 2019
Received: August 30, 2019

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,

For 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)*
K192112

Device Name
FlexBand, FlexPatch, and FlexBand Plus

Indications for Use *(Describe)*

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

Artelon® FlexBand, FlexPatch, and FlexBand Plus are also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons.

Artelon® FlexBand, FlexPatch, and FlexBand Plus are not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide mechanical strength for the tendon repair. Artelon® Tissue Reinforcement reinforces 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.

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510(k) Summary:

Submitter:	International Life Sciences DBA Artelon® 2252 Northwest Pkwy SE, Suite G Marietta, GA 30067
Date Prepared	July 31, 2019
Contact Person:	Tiffini Wittwer, MPH Director Regulatory Affairs Phone: 707.799.6732 E-mail: twittwer@mededge.io
Trade Name:	FlexBand Plus™
Common Name:	Mesh, Surgical, Polymeric devices
Classification:	Class II
Product Code:	FTL, 21 CFR 878.3300
Predicate Device(s):	The subject device is equivalent to the following devices: • K071887 – FlexBand™ (formerly called Artelon® Tissue Reinforcement)
Device Description:	FlexBand™ and FlexBand™ Plus products are a knitted mesh made from ARTELON® fibers. Artelon® fiber is made of polycaprolactone-based polyurethaneurea. The construction permits the mesh to be cut into any desired shape or size without unraveling. The Flexband Plus™ devices have a suture attached to each end of the ARTELON® mesh strips. The pre-loaded suture is intended to improve usability in the operating room. The sutured FlexBand™ Plus is packaged with two commercial (off-the-shelf) stainless steel passing needles. The device is supplied sterile, one product per package, in double layer peel pouch packaging. The FlexBand™ and FlexBand Plus™ devices are available in several sizes; 0.03cm, 0.05cm, and 0.07cm widths in lengths of 8cm, 16cm, and 34cm for each width.
Indication for Use:	Artelon® FlexBand, FlexPatch, and FlexBand Plus Tissue Reinforcement products are intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. Artelon® FlexBand, FlexPatch, and FlexBand Plus are also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Artelon® FlexBand, FlexPatch, and FlexBand Plus are not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone,

	provide mechanical strength for the tendon repair. Artelon® Tissue Reinforcement reinforces soft tissue and provides a degradable scaffold that is incorporated into the patient's own tissue.
Technological Characteristics:	The devices are used in surgical procedures where soft tissue reinforcement is needed. During the surgical procedure the user will suture the device to the desired soft tissues. The material provides a physical scaffold and degrades over time leaving the healed intact tissue in place. The differences between the predicate and the subject device, is the addition of pre-attached sutures to the end of each device and the addition of a backing card to hold the device in the packaging. The predicate and subject devices are available in the exact same sizes.

	FlexBand™ Plus (Subject Device)	**Artelon Tissue Reinforcement (Predicate Device)**	**Analysis of Difference**
510(k) Number Decision Date	To be determined	K071887	
Manufacturer	International Life Sciences	International Life Sciences	
Classification	Class II	Class II	
Product Code	FTL	FTL	
Regulation	21 CFR 878.3300	21 CFR 878.3300	
Indications for Use	Same	Artelon® Tissue Reinforcement is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. Artelon® Tissue Reinforcement is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Artelon® Tissue Reinforcement is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide	

		mechanical strength for the tendon repair. Artelon® Tissue Reinforcement reinforces soft tissue and provides a degradable scaffold that is incorporated into the patient's own tissue.	
Intended Use	Same	Soft tissue reinforcement	
Material	Same	polycaprolactone-based polyurethaneurea	
Available Sizes	Same	0.3 x 8cm 0.3 x 16 cm 0.3 x 32 cm 0.5 x 8 cm 0.5 x 16 cm 0.5 x 32 cm 0.7 x 8 cm 0.7 x 16 cm 0.7 x 32 cm	
Suture Attached	Yes	No	Suture retention testing, suture strength testing, and user validation testing demonstrate that the difference does not create additional risk to safety and effectiveness of the subject device
Packaging Configuration	Device is placed on backing card and put into pouch	Device is placed directly in pouch	Transit testing and packaging validation demonstrate that the difference does not create additional risk to safety and effectiveness of the subject device
Sterilization Method	Same	E-Beam	
Single Use Only	Same	Yes	

Risk Analysis:	A risk analysis was performed for the modifications done for the subject device, in accordance to ISO 14971:2012 Medical Devices – Applications of Risk Management to Medical Devices and International Life Sciences Risk Management SOP. Possible risks were identified which resulted from the addition of suture and packaging. Based on risk identification, verification and validation activities were carried out to ensure the risk acceptability criteria have been met and the risks have been mitigated. All testing was performed on sterilized product.
Performance Testing:	Based on the risks identified, the following tests were performed on the FlexBand Plus™:

	• Suture retention testing • Suture strength testing • Dimensional testing • Transit testing • Packaging testing
Conclusions:	The changes made to the previously cleared FlexBand™ devices do not raise different questions regarding the safety and effectiveness of the device. FlexBand Plus™ is substantially equivalent to the predicate devices. This conclusion is based upon the devices' identical intended use, indications for use, principles of operation, fundamental scientific technology, and performance specifications. The changes made were tested using the same acceptance criteria as the predicate device and demonstrated that there are no new risks and the device is substantially equivalent. The conclusions of testing demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.