April 9, 2026

International Life Sciences
Rachel Roberts
Sr. Staff Specialist, Regulatory Affairs
8601 Dunwoody Pl #250
Sandy Springs, Georgia 30350

Re: K260317
Trade/Device Name: Artelon Convenience Kits
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: QWJ, OWW, MBI
Dated: January 30, 2026
Received: January 30, 2026

Dear Rachel Roberts:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260317

Please provide the device trade name(s).

Artelon Convenience Kits

Please provide your Indications for Use below.

FlexBand, FlexPatch, and FlexBand Plus:
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 provide a degradable scaffold that is incorporated into the patient's own tissue.

Twist and FlexBand Anchors:
The Twist and FlexBand Anchors are indicated for attachment of soft tissue to bone. This product is intended for the following indications:
• Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair.
• Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Illiotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.
• Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.
• Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment.
• Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.
• Hip: Acetabular labral repair.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY: ARTELON CONVENIENCE KITS

(a)(1).	Submitted by:	International Life Science 8601 Dunwoody Pl #250 Sandy Springs, GA 30350
	Date:	January 30, 2026
	Contact Person:	Rachel Roberts Senior Regulatory Staff Specialist (901) 302-5801
	Secondary Contact:	Leslie Fitch Director of Regulatory Affairs
(a)(2).	Proprietary Name:	Artelon Convenience Kits
	Common Name:	Surgical Mesh & Smooth or threaded metallic bone fixation fastener
	Classification Name and Reference:	21 CFR 878.3300 & 21 CFR 888.3040 – Class II
	Device Product Code, Device Panel:	QWJ, OWW, MBI
(a)(3).	Primary Predicate Device(s):	FlexBand, FlexPatch, and FlexBand Plus (K230316) and ATL Anchors (K200503)

(a)(4). Device Description

The subject device, Artelon convenience kits, contains implants and instrumentation for surgical procedures for soft tissue reinforcement and soft tissue fixation to bone. The kits include suture, FlexBand or Twist anchors, FlexBand Dynamic Matrix implants, and instrumentation. The names of the Artelon convenience kit options are FlexBand Fix Kit, FlexBand Solo Kit, FlexBand Multi Kits, FlexBand Twist Kits, FlexBand Drill Kits, and FlexBand Twist Driver Kits. The implants in the kits are the FlexBand or FlexBand Plus, Twist, or FlexBand anchors, which are the same or similar products as cleared under K230316 and K200503. The implants may be sold individually without being included in a convenience kit. The subject device instrumentation includes drill bits, tissue protectors, drivers, drill guides, inserter, K-wires, and anchor caddy.

(a)(5). Indications 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 provide a degradable scaffold that is incorporated into the patient's own tissue.

The Twist and FlexBand Anchors are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

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• Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Illiotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.

• Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.

• Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment.

• Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.
• Hip: Acetabular labral repair.

(a)(6). Technological Characteristics Comparison

For the subject device (FlexBand and FlexBand Plus), there are no changes to the indications for use, product codes, principle of operation, or implant materials. The subject devices have the same design and range of sizes as the predicate device (K230316). The subject devices (FlexBand and Twist anchors) have the same range of sizes and are a similar design as the predicate device (K200503). An alternative sterilization method, EtO, is included in this submission for the subject device kits.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Non-clinical performance bench testing (mesh molar mass characterization, mesh suture retention, mesh tensile testing, anchor pull-out strength, mesh + anchor pull-out strength, anchor insertion and removal torque, and anchor torque to failure) was performed to demonstrate equivalence to the predicate devices. Bacterial endotoxin testing, sterilization testing, and packaging testing information was also provided.

(b)(2). Substantial Equivalence - Clinical Evidence

N/A – Clinical testing was not necessary for the determination of substantial equivalence.

(b)(3). Substantial Equivalence – Conclusions

The evaluation performed and supporting documentation within this submission demonstrates that the subject device, Artelon convenience kits, are comparable to the predicate devices. In conclusion, based on similarities between the indications for use, intended use, principles of operation, materials, design, size offerings, shelf life, product codes, the subject device, Artelon convenience kits, are substantially equivalent to and is as safe and effective as, the legally marketed predicate devices, FlexBand, FlexPatch, and FlexBand Plus (K230316) and ATL Anchors (K200503).