September 2, 2020

International Life Sciences
Tiffini Wittwer
VP, Quality, Clinical, Regulatory
2252 Northwest Parkway SE Suite G
Marietta, Georgia 30067

Re: K200503
Trade/Device Name: ATL Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 22, 2020
Received: July 29, 2020

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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200503

Device Name
ATL Anchors

Indications for Use *(Describe)*
The ATL 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.

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 – K200503

Submitter:	International Life Sciences
Contact Person:	Tiffini Wittwer VP of QA, CA, RA 2252 Northwest Pkwy SE Suite G Marietta GA 30067 Phone: 707.799.6732 E-mail: twittwer@mededge.io
Trade Name:	ATL Anchors
Common Name:	Smooth or threaded metallic bone fixation fastener
Classification:	Class II
Product Code:	MBI
Regulation	21 CFR 888.3040
Predicate Device(s):	The subject device is equivalent to the following devices: • Parcus Knotless PEEK and PEEK CF Push-In Suture Anchors – K193295 • Smith and Nephew BIORAPTOR Knotless Suture Anchor – K093428
Device Description:	The ATL Anchors are press fit suture anchors designed to secure the implant in bone and provide suture fixation. There are two configurations: with and without an eyelet. The devices are made from PEEK, are provided sterile, and pre-mounted on a single-use driver. The devices are provided with USP 0 ultra-high molecular weight polyethylene (UHMWPE) suture. ATL Anchors are used with Artelon® provided cannulated or solid stainless-steel drill bits. The devices are tapped into a pilot hole using a standard mallet (not provided).

Indication for Use:	The ATL 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.
Technological Characteristics:	The ATL Anchors are identical in intended use, principles of operation (push / tap in), and material to both predicate devices. Both the subject device and the predicates are provided preloaded onto an insertion tool with suture. The proposed device and predicates are similar in size, configurations, and packaging. The subject device differs from the predicates in retention feature (helical versus radial grooves), driver mating feature (hexalobe versus square), and the subject device does not have a suture locking feature whereas the predicate, Smith and Nephew Bioraptor, does. Performance bench testing demonstrates that these differences do not raise new questions of safety and efficacy of the ATL Suture Anchor when compared to the predicates.

Summary Performance Data:	Performance data demonstrated that the ATL Anchors met performance specifications and are comparable to the predicate. ATL Anchors met specification for insertion strength, pull-out strength, and cyclic loading. Side by side testing with the predicates was performed for pull-out strength (Parcus Knotless PEEK) and cyclic loading (Smith and Nephew Bioraptor). A sterilization validation and routine sterilization has been established in accordance with ISO 11137-1:2006 (R2015) and ISO 11137-2:20113 (R2019). Shelf-life of the ATL Anchors has been established in accordance with ASTM D4169:2016 and ASTM F1980:2016. The biocompatibility of the ATL Anchor was evaluated against the requirements per ISO 10993-1:2018. All acceptance criteria were met. Bacterial endotoxin testing was completed and met acceptable endotoxin limits per ANSI/AAMI/ ST72:2011. Based on the above testing and information, the ATL Anchor is considered substantially equivalent to the predicates and other currently marketed devices.