November 25, 2020

Fusion Orthopedics, LLC
Kolby Black
4135 S. Power Rd., Suite 110
Mesa, Arizona 85212

Re: K193377/S001
Trade/Device Name: TopLock Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 28, 2020
Received: October 30, 2020

Dear Mr. Black:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193377

Device Name
TopLock Anchor System

Indications for Use *(Describe)*
The TopLock Anchor System is intended to secure soft tissue to bone of:

The Shoulder:
Bankart Repair, SLAP Lesion Repair, Acromio-Clavicular Separation, Rotator Cuff Repair, Capsule Repair, Biceps Tenodesis, Deltoid Repair

The Elbow:
Ulnar or Radial Collateral Ligament Reconstruction, Bicep Tendon Reconstruction, Tennis Elbow Repair

The Hand and Wrist:
Scapholunate Ligament Reconstruction, Ulnar / Radial Collateral Ligament Reconstruction, Extensor Tendon Repair, Flexor Tendon Repair

The Knee:
Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Tendon Repair

The Ankle and Foot:
Lateral Ligament Stabilization Repair, Medial Ligament Stabilization Repair, Achilles Tendon Repair / Reconstruction, Metatarsal Ligament Repair, Hallux Valgus Reconstruction, Mid and Rear Foot Reconstruction

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: TopLock Anchor System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	November 24, 2020
Submitted By	Fusion Orthopedics, LLC 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876
Primary Contact	Kolby Black 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876 Tele e-mail: FDA@fusionorthopedics.com
Trade Name	TopLock Anchor System
Submission Number	K193377
Classification Name	Fastener, Fixation, Non-degradable, Soft Tissue
Class	II
Product Code	MBI
CFR Section	21 CFR Section 888.3040
Device Panel	Orthopedic
Primary Predicate Device	Core Essence reNOVO Suture Anchors (K071520)
Secondary Predicate Device	Arthrex PEEK Mini PushLock Anchors (K101679)
Reference Devices	Core Essence Orthopaedics, Inc., TAC-tite™ PEEK (K111716) Parcus Medical Twist & Triple Twist PEEK Screw-In Suture Anchors (K120942) Parcus Medical PEEK CF Push-In Anchors (K102162)
Device Description	The TopLock Anchor System consists of a collection of barbed suture anchors, manufactured from medical grade Polyetheretherketone or PEEK (ASTM F2026). The anchors are offered from diameters of 3.5mm to 5.0mm with each size offering two eyelet size options to accommodate suture and suture tape. The size range and configurations are offered for surgical treatment of ligament, tendon and soft tissue pathologies of the shoulder and other joints. The specialized instruments are made primarily of surgical grade stainless steel (ASTM F899).
Indications for Use	The TopLock Anchor System is intended to secure soft tissue to bone of: The Shoulder: Bankart Repair SLAP Lesion Repair Acromio-Clavicular Separation Rotator Cuff Repair

	Capsule Repair Biceps Tenodesis Deltoid Repair The Elbow: Ulnar or Radial Collateral Ligament Reconstruction Bicep Tendon Reconstruction Tennis Elbow Repair The Hand and Wrist: Scapholunate Ligament Reconstruction Ulnar / Radial Collateral Ligament Reconstruction Extensor Tendon Repair Flexor Tendon Repair The Knee: Medial Collateral Ligament Repair Lateral Collateral Ligament Repair Posterior Oblique Ligament Repair Extra Capsular Reconstruction Iliotibial Band Tenodesis Patellar Tendon Repair The Ankle and Foot: Lateral Ligament Stabilization Repair Medial Ligament Stabilization Repair Achilles Tendon Repair / Reconstruction Metatarsal Ligament Repair Hallux Valgus Reconstruction Mid and Rear Foot Reconstruction
Materials	Polyetheretherketone (PEEK) (ASTM F2026) Ultra High Molecular Weight Polyethylene Suture (UHMWPE) (ASTM F2848) Stainless Steel (ASTM F899) Aluminum (ASTM B209) Nylon
Substantial Equivalence Claimed to Predicate Devices	The TopLock Anchor System is substantially equivalent to the predicate devices in terms of design, materials used, mechanical safety and performances.
Non-clinical Test Summary	Validations were performed on the cleaning, packaging and sterilization of the implants and associated surgical instruments. Mechanical Testing was performed to show design equivalence including insertion testing, axial pull-out testing, cyclic fatigue testing, and post fatigue pullout testing. Pyrogenicity was evaluated using the Limulus amebocyte lysate (LAL) assay. The testing demonstrated that the subject device meets the recommended maximum endotoxin levels of 20 (EU)/Device.
Clinical Test Summary	No clinical studies were performed.
Conclusions: Non- clinical and Clinical	Fusion Orthopedics LLC considers the TopLock Anchor System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.