U & I Corporation
Bo-Ram Kang
RA Specialist
20, Sandan-ro 76beon-gil(Rd)
Uijeongbu-si, KR 11781 Gyeonggi-do

August 9, 2018

Re: K180759
Trade/Device Name: SECULOK™ Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 10, 2018
Received: July 13, 2018

Dear Ms. Kang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180759

Device Name
SECULOK™ Suture Anchor

Indications for Use *(Describe)*
SECULOK™ Suture Anchor is for fixation or reattachment of soft tissue including ligament and tendon to bone especially with below indications.

- Shoulder:
Bankart repair, SLAP lesion repair, Acromio-Clavicular separation repair, Rotator Cuff repair, Capsular shift or Capsulolabral reconstruction, Biceps tenodesis, Deltoid repair.

- Foot/Ankle:
Medial or lateral stabilization, Achilles tendon repair.

- Elbow/Wrist/Hand:
Ulnar or Radial collateral ligament reconstruction, Lateral epicondylitis repair, Biceps tendon reattachment.

- Knee:
Extra-capsular repairs: Medial/lateral collateral ligament repair, posterior oblique ligament repair, Iliotibial band tenodesis
Patellar realignment and tendon repairs : Vastus medialis obliquous advancement

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

Manufacturer: U & I Corporation
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 11781, Korea,

Sponsor: U & I Corporation
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 11781, Korea,

Sponsor Contact: Bo-Ram Kang, Regulatory Affairs Specialist
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brkang@youic.com

Date Prepared: July 10, 2018

Device Name: Trade Name: SECULOK™ Suture Anchor

Classification Name: Fastener, Fixation, nonbiodegradable, soft tissue
(21 CFR §888.3040)

Common Name: Fastener, Fixation, Nondegradable, Soft Tissue

Product Code: MBI

Predicate Devices: Stryker PEEK ZIP Anchor (K070758) [Primary]
CONMED CrossFT BC Suture Anchor (K101100)
Stryker ReelX STT® Knotless Anchor System (K120824)
Arthrex PushLock™(K101679)

Description of Device:

The SECULOK™ Suture Anchor consists of two types, Suture Anchor and Knotless Anchor.

The Suture Anchor is an implant used for fixation of sutures into bone. The implant is made of PEEK (ASTM F2026) and works with preloaded 1 ~ 3 USP#2 size sutures (Ultra High Molecular Weight Polyethylene(UHMWPE, ASTM F2848)). The Suture Anchor is provided sterile as single package including the implant and inserter for users to use without additional process of sterilization in hospitals.

The Knotless Anchor is an implant used for fixation of sutures into bone. The implant is made of PEEK (implant body) and Titanium alloy (tip, ASTM F136) and fixate the USP #2 sutures without knotting. The Knotless Anchor is provided sterile as single package including the implant and inserter for users to use without additional process of sterilization in hospitals.

The SECULOK™ Suture Anchor comes preloaded on a disposable inserter made

from surgical grade stainless steel and ABS plastic. The entire product is packaged in a box with a Tyvek® lid, and blister the finished product is sterilized by ethylene oxide. Both the implant, suture and inserter are designed for single use only and supplied non-pyrogenic.

Indications for Use:

SECULOK™ Suture Anchor is for fixation or reattachment of soft tissue including ligament and tendon to bone especially with below indications.

- Shoulder:
  Bankart repair, SLAP lesion repair, Acromio-Clavicular separation repair, Rotator Cuff repair, Capsular shift or Capsulolabral reconstruction, Biceps tenodesis, Deltoid repair.

- Foot/Ankle:
  Medial or lateral stabilization, Achilles tendon repair.

- Elbow/Wrist/Hand:
  Ulnar or Radial collateral ligament reconstruction, Lateral epicondylitis repair, Biceps tendon reattachment.

- Knee:
  Extra-capsular repairs: Medial/lateral collateral ligament repair, posterior oblique ligament repair, Iliotibial band tenodesis
  Patellar realignment and tendon repairs : Vastus medialis obliquous advancement

Substantial Equivalence:

The SECULOK™ Suture Anchor is described for each type as below:

(1) Suture Anchor

The Suture Anchor is substantially equivalent to PEEK ZIP Anchor (K070758) and CrossFT BC Suture Anchor (K101100).

The Suture Anchor and CrossFT BC Suture Anchor are different in material, but suture Anchor is substantially equivalent to CrossFT BC Suture Anchor(K101100) in mechanical performance. The primary predicate device is the Stryker PEEK ZIP Anchor, and the others are additional predicate device.

(2) Knotless Anchor

The Knotless Anchor is substantially equivalent to ReelX STT® Knotless Anchor System (K120824) and PushLock™ (K101679).

The Knotless Anchor and PushLock™(K101679) are also different in material, but the Knotless Anchor is substantially equivalent to PushLock™ (K101679))

in mechanical performance. The primary predicate device is the ReelX STT® Knotless Anchor System, and the others are additional predicate device.

1. Comparison Technological Characteristics with the predicate device

The predicate and proposed devices have the similar intended use and basic fundamental scientific technology and share the following similarities;

- The similar indications for use
- Similar design features
- PEEK implantable bone screw and non-absorbable sutures
- Ability to secure soft tissue to bone during reconstructive procedures
- The equivalent mechanical performance

2. Performance Testing

The SECULOK™ Suture Anchor was tested in a non clinical setting (bench testing) to assess that to no new safety and efficiency issues were raised with this device.

The Suture Anchor was performed torsional properties, driving torque, axial pullout strength, axial pullout fatigue test.

The Knotless Anchor was performed axial pullout strength.

The all tests met all acceptance criteria and that verifies performance of the SECULOK™ Suture Anchor is substantially equivalent to predicate devices. The acceptance criteria for performance testing were developed using the data of the primary predicate, CrossFT BC Suture Anchor (K101100) and PushLock™ (K101679).

The following tests were performed:

1) Suture Anchor
   (1) Torsional Properties test according to ASTM F543-17
   (2) Driving torque test according to ASTM F543-17
   (3) Axial pullout strength test according to Premarket Notification (510(k)) Submissions for Bone Anchors Draft Guidance (January 3, 2017)
   (4) Axial pullout fatigue test according to Premarket Notification (510(k)) Submissions for Bone Anchors Draft Guidance (January 3, 2017)

2) Knotless Anchor
   (1) Axial pullout strength test according to Premarket Notification (510(k)) Submissions for Bone Anchors Draft Guidance (January 3, 2017)

(2) Axial pullout fatigue test according to Premarket Notification (510(k)) Submissions for Bone Anchors Draft Guidance (January 3, 2017)

3) Suture

(1) Tensile strength test according to USP 29 <881>

3. Sterilization Data

The sterilization parameters for the SECULOK™Suture Anchor device comply with the requirements prescribed in the applicable standards for ethylene oxide sterilization (ISO 11135-1:2014 “Sterilization of health care products -- Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices” and ISO 10993-7:2008 “Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals”). The sterilization cycle ensures a SAL of 10^{-6}. The EtO residuals were below the limits specified in the standard.

4. Conclusion

The data and information provided in this submission support the conclusion that the SECULOK™ Suture Anchor is substantially equivalent to predicate devices with respect to indications for use and technological characteristics.