March 4, 2020

CoNextions Medical
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K200028
Trade/Device Name: Coronet Soft Tissue Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 6, 2020
Received: January 6, 2020

Dear Ms. Hogan:

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 Rose, Ph.D.
Acting 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 on last page

510(k) Number *(if known)*

K200028

Device Name

Coronet Soft Tissue Fixation System

Indications for Use *(Describe)*

Coronet Soft Tissue Fixation System is intended for fixation of tissue to bone and tissue to tissue.

This product is intended for the following indications:

- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar and Radial Ligament Reconstruction
- Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar and Radial Ligament 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.

K200028
510(k) SUMMARY
CoNextions Medical's Coronet Soft Tissue Fixation System

Applicant Information

Manufacturer: CoNextions Medical, Inc
150 North Wright Brothers Drive, Suite 560
Salt Lake City, Utah 84116
Ph: 201.419.0118
F: 801.436.5369

Contact Person: Matthew Swift, Director of Marketing

Date Prepared: March 2, 2020

Device Information

Proprietary Name: Coronet Soft Tissue Fixation System

Common Name: Soft Tissue Fixation Device

Classification Name: MBI (888.3040) Fastener, fixation, nondegradable, soft tissue

Predicate Devices: K162429 ZipE Knotless Tissue Repair and Attachment Devices, Ziptek LLC. (Primary)
K070882 TwinLoop™-PEEK Anchor, Stryker, Inc.
K013806 Synthes® Metallic Spiked Washer, Depuy Synthes, Inc.
K130033 ToggleLoc™ System, Zimmer Biomet, Inc.

Device Description

The Coronet Soft Tissue Fixation System consists of a single-use, sterile implant used to fixate tissue to bone and tissue to tissue. The implant consists of an anchor and soft tissue washer interconnected via a continuous loop of suture. The implant comes pre-assembled to an inserter, which facilitates concurrent placement of the anchor and soft tissue washer. A drill bit is provided to allow for the creation of a properly sized pilot hole in the bone implantation site.

Intended Use/Indications for Use

Coronet Soft Tissue Fixation System is intended for fixation of tissue to bone and tissue to tissue.

This product is intended for the following indications:

- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair
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- Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar and Radial Ligament Reconstruction

Technological Characteristics

Coronet Soft Tissue Fixation System is substantially equivalent to other legally marketed bone anchor devices. Specifically, use of an anchor for bone attachment with a washer for soft tissue attachment is substantially equivalent to the ZipE® Knotless Tissue Repair and Attachment Device from Ziptek LLC (K162429). Coronet and the ZipE device are similar in design, and have same intended use, same specific indications, similar technological characteristics and similar principles of operation. The anchor component of Coronet is equivalent to the TwinLoop™-PEEK Anchor from Stryker, Inc. (K070882), which has the same intended use, similar specific indications, similar technological characteristics and similar principles of operation. The soft tissue washer component of Coronet is equivalent to the Synthes® Spiked Metallic Washer from Depuy Synthes, Inc (K013806) which has a similar intended use and similar technological characteristics and principles of operation. Benchtop testing comparing Coronet to the ZipE and TwinLoop predicates demonstrates the Coronet system is substantially equivalent and introduces no new for different questions of safety or effectiveness.

Performance Data

The following non-clinical testing was conducted on Coronet Soft Tissue Fixation System.

Testing Category	**Specific Tests Performed**
Bench Testing	Static pullout testing Cyclic testing Insertion testing Fatigue limit testing
Human Factors	End-user validation
Biocompatibility Testing	Cytotoxicity Sensitization Irritation Pyrogen testing MEM elution testing Acute system injection Intramuscular implantation
Sterilization validation	Bioburden Relative resistance EO residual testing Endotoxin (LAL) validation
MR Compatibility	Induced displacement testing Induced torque testing Induced heating testing

	Image artifact testing
Packaging	Package integrity tests Accelerated aging

Conclusions

The Coronet Soft Tissue Fixation System is substantially equivalent to predicate devices with respect to its indications for use, design, and function. The minor technological differences between Coronet and the predicate devices raise no new or different questions of safety or effectiveness and do not adversely impact the performance or function of the device as confirmed by performance testing. Thus, Coronet is substantially equivalent to the predicates.