ICONN Orthopedics, LLC
Whitt Israel
CEO
400 Union Hill Drive, Suite 150
Birmingham, Alabama 35209

November 29, 2017

Re: K172491
Trade/Device Name: ICONN Square 2.5MM 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: October 31, 2017
Received: November 1, 2017

Dear Whitt Israel:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

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)*
K172491

Device Name
ICONN Square 2.5MM Suture Anchor

Indications for Use *(Describe)*
The ICONN Square Suture Anchor System is intended to provide secure fixation of soft tissue to bone in orthopedic procedures where fixation is needed as a result of injury or degenerative disease. The system is designed for use in the hip, shoulder, foot, ankle, elbow, wrist, hand, and knee for the following indications:

Hip Indications: Capsule Repair, Acetabular Labrum Reattachment

Shoulder Indications: Capsular Stabilization, Bankart Repair, Anterior Shoulder Instability, SLAP Lesion Repair, Capsular Shift or Capsulolabral Reconstruction, Acromioclavicular Separation Repair, Deltoid Repair, Rotator Cuff Repair, Biceps Tenodesis.

Foot/Ankle Indications: Hallux Valgus Repair, Medial or Lateral Instability Repair/Reconstruction, Midfoot Reconstruction, Metatarsal Ligament/Tendon Repair/Reconstruction, Bunionectomy.

Elbow, Wrist, and Hand: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair.

Knee: Extra Capsular Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Patellar Realignment and Tendon Repair, Vastus Medialis Obliquous Advancement, Iliotibial Band Tenodesis.

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.

400 Union Hill Drive, Suite 150
Birmingham, AL 35209

510(k) SUMMARY

Submitter's Name:	ICONN Orthopedics, LLC
Submitter's Address:	400 Union Hill Drive Suite 150 Birmingham, AL 35209
Submitter Contact Person:	Whitt Israel CEO (205) 913-2068
Date Summary was Prepared:	November 27, 2017
Trade Name or Proprietary Name:	ICONN Square 2.5MM Suture Anchor
Common or Usual Name:	Suture Anchor
Classification:	Class II per 21 CFR §888.3040
Product Code:	MBI - Fastener, Fixation, Nondegradable, Soft Tissue
Classification Panel:	Division of Orthopedic Devices

Device Description:

The ICONN Square 2.5MM Suture Anchors (P/N 125000) are sterile (gamma irradiation), single use implantable devices made from Solvay's Zeniva® ZA-500 polyetheretherketone (PEEK) material intended to provide secure fixation of soft tissue to bone in orthopedic procedures where fixation is needed as a result of injury or degenerative disease. The anchors are available in one size (Width x Length): 2.5mm x 7.95mm and can be used as a knotted or knotless anchor.

Intended Use:

The ICONN Square Suture Anchor System is intended to provide secure fixation of soft tissue to bone in orthopedic procedures where fixation is needed as a result of injury or degenerative disease. The system is designed for use in the hip, shoulder, foot, ankle, elbow, wrist, hand, and knee for the following indications:

Hip Indications: Capsule Repair, Acetabular Labrum Reattachment.

Shoulder Indications: Capsular Stabilization, Bankart Repair, Anterior Shoulder Instability, SLAP Lesion Repair, Capsular Shift or Capsulolabral Reconstruction, Acromioclavicular Separation Repair, Deltoid Repair, Rotator Cuff Repair, Biceps Tenodesis.

Foot/Ankle Indications: Hallux Valgus Repair, Medial or Lateral Instability Repair/Reconstruction, Midfoot Reconstruction, Metatarsal Ligament/Tendon Repair/Reconstruction, Bunionectomy.

Elbow, Wrist, and Hand: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair.

Knee: Extra Capsular Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Patellar Realignment and Tendon Repair, Vastus Medialis Obliquous Advancement, Iliotibial Band Tenodesis.

Predicate Devices:

Two predicate devices from two manufacturers were used to help demonstrate substantial equivalence of several characteristics to include intended use, design, sizes, PEEK material, supplying the device in the sterile state, and provision of sutures. The predicate devices are:

- Smith & Nephew, Inc. BIORAPTOR 2.3PK Suture Anchor, Model 72201542 (K121018)
- Arthrex 2.9mm Short PEEK Pushlock Suture Anchor, Model Number AR-2923PS (K063479)

Both predicates are intended for soft tissue fixation to bone for the same indications listed for the ICONN Square 2.5MM Suture Anchor. The ICONN 2.5MM Square Suture Anchor knot configuration was compared to the predicate of the same category (BIORAPTOR 2.3PK for knotted configuration and 2.9mm Short PEEK Pushlock for the knotless configuration).

As well, the ICONN Answer Suture Anchor (K132724) was used as a predicate device to demonstrate substantial equivalence as it relates to biocompatibility of the subject device.

Technological Characteristics:

The ICONN Square 2.5MM Suture Anchor System suture anchors are of similar design to the predicates and are manufactured with the same basic material in similar size. The differences are in the manner in which the suture is secured to the anchor. The Smith and Nephew BIORAPTOR 2.3PK includes a single, integral eyelet that is used to secure the suture and the Arthrex 2.9mm Short PEEK Pushlock uses a separate eyelet with a cannulated anchor design to secure the suture. The ICONN Square 2.5MM Suture Anchor is designed to have the suture wrap through one of two integral eyelets to secure the suture. Due to the design differences, performance testing was conducted to characterize the performance of the ICONN Square 2.5MM Suture Anchor in comparison to the predicate devices.

Performance Data:

The FDA's *Draft Guidance Document for Testing Bone Anchor Devices* (April 20, 1996) was used for guidance in side by side mechanical testing performed on the subject device and predicates for the following test modes:

- Anchor displacement after cyclic loading

- Ultimate anchor pull-out

Testing showed that the ICONN Square 2.5mm Suture Anchor performed similarly or better than the predicates or within acceptable ranges for the intended use.

Insertion testing was also conducted on the subject device to demonstrate that the device can be safely implanted.

Conclusion: The ICONN Square 2.5MM Suture Anchor is substantially equivalent to the predicates and does not raise different questions of safety and effectiveness.