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

August 9, 2018

Re: K181680
Trade/Device Name: ICONN Answer II 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: June 22, 2018
Received: June 26, 2018

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. 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,

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)*
TBD

Device Name
ICONN Answer II Suture Anchor

Indications for Use *(Describe)*
The ICONN Answer II Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, foot, and ankle. Specific indications are as follows:

Shoulder Indications: Rotator Cuff Repairs, Biceps Tenodesis

Foot/Ankle Indications: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament 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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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:	June 22, 2018
Trade Name or Proprietary Name:	ICONN Answer II Suture Anchor
FDA Submission Document Number:	K181680
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 Answer II Suture Anchor (P/N's 147501 and 155001) is a sterile (gamma irradiation), single use implantable device made from Solvay's Zeniva® ZA-600L polyetheretherketone (PEEK) material indicated for soft tissue reattachment procedures in the shoulder, foot, and ankle. The anchor is available in two sizes (Diameter x Length): 4.75mm x 16mm and 5.5mm x 16mm.

Intended Use:

The ICONN Answer II Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, foot, and ankle. Specific indications are as follows:

Shoulder Indications: Rotator Cuff Repairs, Biceps Tenodesis.

Foot/Ankle Indications: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair.

Predicate Device:

The predicate device was selected 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 device is listed below:

- Arthrex PEEK Corkscrew FT (K061665)

Technological Characteristics: The ICONN Answer II Suture Anchor System suture anchors are of similar design to the predicate and are manufactured with the same basic material in similar sizes.

Performance Data: Performance testing was conducted for both pullout characteristics and torsional properties. For pullout characteristics, 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 predicate for the following test modes:

- Anchor displacement after cyclic loading
- Ultimate anchor pull-out

Pullout testing showed that the ICONN Answer II Suture Anchor performed similarly or better than the predicates or within acceptable ranges for the intended use. For insertion testing, ASTM F543-2013 was followed, specifically the sections on torsional properties (section A1 of the standard) and driving torque (section A2 of the standard) were analyzed and compared to demonstrate the device can be safely implanted.

Cytotoxicity, irritation, and sensitization testing were carried out in accordance with ISO 10993/(R)2013 and all testing met acceptance criteria. For cytotoxicity, all test articles resulted in a cytotoxicity score of zero (0) with an acceptance criteria of 2 or less. For irritation, a score difference of 0.0 for the SC extract and 0.1 for the SO extract was seen, with an acceptance criteria of 0.2 or less. For sensitization, the test article extracts showed no evidence of causing delayed dermal contact sensitization, which is also the acceptance criteria.

In accordance with ANSI/AAMI ST72:2016 LAL testing was conducted using the Kinetic-Chromogenic assay and the results demonstrated the test articles were <0.05 EU/device, which met acceptance criteria of < 20 EU/device. Material-mediated pyrogenicity testing was conducted and the device was determined to be non-pyrogenic.

Sterilization validation testing (Bioburden Recovery, Bioburden – 3 Lots, Bacteriostasis/Fungistasis, and Sterility) was carried out and met acceptance criteria. Bioburden Recovery was 51.5% (used as an adjustment factor for bioburden data, so no acceptance criteria were required for this test). Bioburden testing resulted in <3.9 CFU/device for all three lots, which met acceptance criteria of <1,000 CFU/device. B/F results demonstrated no inhibition from the test article with all three challenge organisms showing positive growth on both subject device and control samples. This met the acceptance criteria of showing no inhibition. Sterility testing

	resulted in zero (0) positive tests of sterility which met acceptance criteria of not more than one (1) positive test of sterility.
Conclusion:	The submitted device has been demonstrated to be as safe, as effective, and performs as well as or better than the predicate device.