December 7, 2018

ICONN Orthopedics, LLC
Whitt Israel
Chief Executive Officer
400 Union Hill Drive, Suite 150
Birmingham, Alabama 35209

Re: K180670
Trade/Device Name: ICONN Campbell Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: November 2, 2018
Received: November 5, 2018

Dear Mr. 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,

Laurence D. Coyne -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)*
K180670

Device Name
ICONN Campbell Interference Screw

Indications for Use *(Describe)*
The ICONN Campbell Interference Screw System is intended for fixation of tissue, including ligament or tendon to bone for the following indications:

Shoulder: Rotator Cuff Repairs, 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, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist, Lateral Epicondylitis 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.

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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:	March 12, 2018
Trade Name or Proprietary Name:	ICONN Campbell Interference Screw
Common or Usual Name:	Interference Screw
Classification:	Class II per 21 CFR §888.3040
Product Code:	HWC – Screw, Fixation, Bone MBI – Fastener, Fixation, Nondegradable, Soft Tissue
Classification Panel:	Division of Orthopedic Devices

Device Description:

The ICONN Campbell Interference Screws (various part numbers) are sterile (gamma irradiation), single use implantable devices available in two materials: Solvay's Zeniva® ZA-600L polyetheretherketone (PEEK) or Ti 6Al-4 ELI (Grade 23) and is intended for fixation of tissue, including ligament or tendon to bone. The screws are available in multiple sizes ranging from diameters of Ø6mm – Ø12mm in 1mm increments. The Ø6mm screw is available only in 20mm long, the Ø7mm - Ø10mm screws are available in 20mm and 25mm lengths, and the Ø11mm and Ø12mm screws are available in 25mm lengths only.

Intended Use:

The ICONN Campbell Interference Screw System is intended for fixation of tissue, including ligament or tendon to bone for the following indications:

Shoulder: Rotator Cuff Repairs, 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, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle.

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis.

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/wrist, Lateral Epicondylitis repair.

Predicate Devices:

The predicate device was selected to help demonstrate substantial equivalence of several characteristics to include intended use, design, sizes, material, and sterility. The predicate device is one product but is available in two materials:

- Arthrex PEEK Interference Screw (K062466)
- Arthrex Titanium Interference Screw (K062466)

The predicate device is intended for fixation of tissue, including ligament or tendon to bone for the same indications listed for the ICONN Campbell Interference Screw.

Technological Characteristics:

The ICONN Campbell Interference Screw System interference screws are of similar design to the predicate and are manufactured with the same basic material in similar sizes. The differences are in the geometric design of the thread profile and the driver/screw interface. The thread geometry of the ICONN Campbell Interference Screws have a squared off base, while the Arthrex screws have a rounded trough. In regard to driver interface, the ICONN Campbell screws have a square shaped driver interface, while the Arthrex screws have a star shaped driver interface. Due to the design differences, performance testing was conducted to characterize the performance of the ICONN Campbell Interference Screw in comparison to the predicate device.

Performance Data:

ASTM F543-2013 was followed in order to compare axial pullout strength (section A3 of the standard) after cyclic loading and displacement between the subject device and predicate device along with insertion characteristics of the subject device. The version of the screw made out of PEEK material was tested, as that material constitutes a worst case between the two materials offered. For cyclic loading and axial pullout comparison, the Arthrex PEEK Interference Screw was tested as it is made out of similar material. For insertion testing, 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.

Testing showed that the ICONN Campbell Interference Screw performed similarly or better than the predicate or within acceptable ranges for the intended use for axial pullout after cyclic loading and displacement during cyclic loading. For insertion, testing results showed that the device can be safely implanted.

Cytotoxicity, irritation, and sensitization, testing were carried in accordance with ISO 10993-1:2009/(R)2013 for the ICONN Campbell Interference Screws for both the PEEK and titanium screws. All testing met acceptance criteria.

In accordance with ANSI/AAMI ST72:2016 LAL testing was conducted using the Kinetic-Chromogenic assay for the ICONN Campbell PEEK and Titanium Interference Screws. One (1) each of the test articles were placed in 10 mL of Water for Injection and extracted at 37°C using a shaker for at least an hour. Positive and inhibition enhancement controls were included. Results of the PEEK and Titanium Interference Screws demonstrated the test articles were < 0.05 EU/device.

Conclusion: The ICONN Campbell Interference Screw is substantially equivalent to the predicate and does not raise different questions of safety and effectiveness.