



August 20, 2020

In2Bones USA, LLC
Christine Scifert
VP of Quality and Regulatory
6000 Poplar Ave, Suite 115
Memphis, Tennessee 38119

Re: K201636

Trade/Device Name: Hercules™ Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 6, 2020
Received: August 7, 2020

Dear Ms. Scifert:

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,

Laura C. Rose, Ph.D.
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K201636

Device Name

Hercules™ Suture Anchor System

Indications for Use (Describe)

The In2Bones Hercules™ Suture Anchors are intended for use in the following applications:

1. Shoulder: Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction.
2. Foot/Ankle: Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot reconstruction.
3. Knee: Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair.
4. Hand/Wrist: Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament reconstruction.
5. Elbow: Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Hercules™ Suture Anchor System
August 14, 2020

Company: In2Bones USA, LLC
6000 Poplar Ave, Suite 115
Memphis, TN 38119
901-260-7931

Primary Contact: Christine Scifert

Company Contact: Rebecca Wahl

Trade Name: Hercules™ Suture Anchor System

Common Name: Fastener, Fixation, Non-Degradable, Soft Tissue

Classification: II

Regulation Number: 21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener

Panel: 87-Orthopedic

Product Code(s): MBI

Device Description: The In2Bones Hercules™ Suture Anchor System is a bone implant device intended for the fixation of soft tissue to bone. This system consists of two anchor styles manufactured from ASTM F 2026 Poly Ether Ether Ketone (PEEK) - Fully threaded anchor and Knotless anchor - that are available in five sizes ranging from 2.0mm to 5.5mm and 4 sizes ranging from 2.5mm to 5.5mm respectively, for use in a range of fixation applications.

Indications for Use:

The In2Bones Hercules™ Suture Anchors are intended for use in the following applications:

1. Shoulder: Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction.
2. Foot/Ankle: Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot reconstruction.

3. Knee: Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair.
4. Hand/Wrist: Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament reconstruction.
5. Elbow: Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction.

Substantial Equivalence: The subject components were demonstrated to be substantially equivalent to the following systems previously cleared by the FDA:

Primary Predicate:

- K110773 and K150715– Tornier Insite FT PEEK Knotless Suture Anchors

Additional Predicates:

- K112237 - Arthrex MicroSuture Anchors
- K071257 and K992487 - Depuy Mitek Mini QUICKANCHOR

Device	In2Bones Hercules™ Suture Anchor System (Subject Device)	Arthrex MicroSuture Anchors (FT Predicate Device)	Depuy Mitek MINI QuickAnchor Plus (Knotless Predicate Device)	Tornier Insite FT Suture Anchor, 2.5mm & 3.5mm; 4.5, 5.5mm, 6.5mm (Predicate Device)
510K #	Subject	K112237	K071257, 992487	K150715, K110773
Intended Use	Secure soft tissue to bone	Secure soft tissue to bone	Secure soft tissue to bone	Secure soft tissue to bone
Indications for Use	<p><u>Foot/Ankle:</u> Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot reconstruction.</p> <p><u>Shoulder:</u> Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction.</p> <p><u>Knee:</u> Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair</p> <p><u>Hand and Wrist:</u> Scapholunate ligament, Radial collateral ligament and Ulnar collateral reconstruction.</p> <p><u>Elbow:</u> Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction.</p>	<p><u>Foot/Ankle:</u> Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, digital tendon transfers, Midfoot reconstruction</p> <p><u>Shoulder:</u> Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction</p> <p><u>Knee:</u> Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis.</p> <p><u>Elbow, Wrist, Hand:</u> Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Biceps Tendon Reattachment, repair/reconstruction of</p>	<p><u>Foot/Ankle:</u> Hallux Valgus reconstruction Midfoot reconstruction</p> <p><u>Shoulder:</u> Bankart Repair</p> <p><u>Wrist, Hand:</u> Scapholunate ligament reconstruction Thumb ulnar or radial collateral ligament</p> <p><u>Pubis:</u> Fixation in the pubis for bladder neck suspension to resolve stress urinary incontinence</p>	<p><u>Foot/Ankle:</u> Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot reconstruction.</p> <p><u>Shoulder:</u> Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction.</p> <p><u>Knee</u> Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair, Hallux Valgus and Midfoot reconstruction.</p> <p><u>Hand/Wrist</u> Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament reconstruction.</p> <p><u>Elbow</u> Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction. Extra Capsular Repairs: Medial, Lateral and Posterior Oblique Ligaments</p>

		collateral ligaments, repair of flexor and extensor tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers, Carpal ligament reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)		Patellar Tendon Repair
Classification Name	Screw, Fastener, Fixation, Nonabsorbable, Bone, Soft Tissue	Screw, Fastener, Fixation, Biodegradable, Soft Tissue	Smooth or threaded metallic bone fixation fastener	Fastener, Fixation, Non-degradable, Soft Tissue, Smooth or Threaded Metallic bone fixation fastener
Product Code	MBI	HWC, MAI, MBI	HWC	MBI
Material	PEEK	Ti, PLA/βTCP	NiTi, Ti6Al4V	PEEK and Titanium
Sizes	2.0mm - 5.5mm	2.2mm-2.7mm	1.8 w/5.5mm arc	2.5mm – 6.5mm
Sutures	Fully Threaded: Pre-threaded Non-absorbable braided polyethylene suture Knotless: Provided separate Non-absorbable braided polyethylene suture	Pre-threaded Non-absorbable polyethylene / polyester suture	Pre-threaded Non-absorbable braided polyethylene suture	Pre-Threaded Non-absorbable braided polyethylene suture

The subject Hercules™ Suture Anchor System made of PEEK is different in some design features compared to the predicates, but have been demonstrated to be substantially equivalent to the previously cleared devices cleared under K150715, K110773 K112237, K071257 and K992487 as the products are similar in indications, materials, sterilization and geometry.

Reference Devices:

- K063778, K092533, K181774 – Teleflex Force Fiber
- K182402 – CoLink View Plating System

Performance Testing:

Non-clinical performance bench testing (mechanical testing) was performed to demonstrate substantial equivalence to the predicate devices per draft Guidance for Premarket Notification (510(k)) for Bone Anchors issued on January 3, 2017, mechanical testing was done in accordance with ASTM F543-07 to evaluate the anchors and establish substantial equivalence. Testing included Anchor Insertion Torque and Torque to Failure, Tensile Pullout, Cyclic Load, and Post-Fatigue Pullout. Bacterial endotoxin testing (LAL) was done per ANSI/AAMI ST72. Sterility validations for EO sterilization per ISO 11135 for the implants and for gamma sterilization per ISO 11137-2 for the instruments were conducted and shelf-life validations were completed and determined to be 5 years. A biocompatibility assessment was done per ISO 10993-1 and any required testing was done per the ISO 10993 standard. Packaging validations were completed in accordance with ISO 11607-1.

Conclusion

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.