January 29, 2020

In2Bones SAS
% Christine Scifert
Regulatory Affairs Director
In2Bones USA
6000 Poplar Avenue, Suite 115
Memphis, Tennessee 38119

Re: K191380
Trade/Device Name: Quantum® Total Ankle Prosthesis
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: December 27, 2019
Received: December 30, 2019

Dear Christine 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,

Ting Song, PhD, RAC
Assistant Director (Acting)
DHT6A: Division of Joint Arthroplasty 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 below.

510(k) Number *(if known)*
K191380

Device Name
Quantum® Total Ankle Prosthesis

Indications for Use *(Describe)*
The Quantum® total ankle prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

Note: In the United States, the ankle prosthesis is intended for cement use only.

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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510(k) SUMMARY
For In2Bones QUANTUM® Total Ankle Prosthesis

Sponsor identification	In2Bones SAS 28 chemin du Petit Bois 69130 Ecully – France Phone: +33.4.72.29.26.26 Fax: +33.4.72.29.26.29
Establishment registration number	3010470577
Date of preparation	December 23, 2019
Contact person	Christine Scifert In2BonesUSA 6000 Poplar Avenue, suite 115 Memphis, TN 38119 Cell: 901-831-8053 Email: christine.scifert@i2b-usa.com
Proprietary Name	QUANTUM® Total Ankle Prosthesis
Common name	Total Ankle Prosthesis
Device classification regulation	21 CFR 888.3110 - Ankle joint metal/polymer semi-constrained cemented prosthesis. Class II
Device Product Code and Panel	HSN 87 orthopedics

Device Description	The QUANTUM® Total Ankle Prosthesis is a fixed-bearing total ankle replacement device. The prosthesis is composed of a tibial implant, a tibial inlay, and a talar implant. Both the tibial implant and talar implant are secured to patient anatomy via bone cement; the intermediate inlay is rigidly fixed to the tibial implant intra-operatively. When all three components are implanted, the intermediate inlay acts as a bearing along the talar implant, enabling movements at the replaced joint. Components are available in a variety of sizes and design configurations to accommodate the various anatomical needs of a patient's ankle joint, and intended for both primary and revision applications. QUANTUM® Total Ankle Prosthesis is accompanied by a complete instrumentation set including trial and drill/cutting guide to assist surgeons in implantation of the device.
Materials	The tibial implant is manufactured from titanium alloy (Ti-6Al-4V ELI) with porous titanium coating on the bone-contacting surface. The tibial inlay is made of Ultra-High-Molecular-Weight Polyethylene. The highly polished talar implant is manufactured from cobalt-chromium alloy (Co-28Cr-6Mo) with porous titanium coating on the bone-contacting surface.
Indications for use:	The QUANTUM® total ankle prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Note: In the United States, the ankle prosthesis is intended for cement use only.
Predicate Devices	Primary predicate: - Salto Talaris (K090076 & K153452), Tornier Additional predicates: - Cadence / Integra Total Ankle Replacement System (K151459), Ascension Orthopedics (acquired by Integra LifeSciences) - Vantage (K152217), Exactech
Comparison of Indications and Technological characteristics and Substantial Equivalence Summary:	The In2Bones QUANTUM® total ankle prosthesis is similar to the predicate devices Salto Talaris (K090076 & K153452), Cadence / Integra Total Ankle Replacement System (K151459) and Vantage (K152217) in indications for use, intended use, design, size ranges, principle of operation and materials.

Summary Performance Data	Performance testing of the QUANTUM® total ankle prosthesis was assessed through mechanical bench testing and Finite element analysis. Assessment included: - Range of Motion study - Contact pressure and constraint evaluation - Component Fatigue analysis - Insert Locking mechanism These tests were performed according to ASTM F2665. - Wear evaluation according to ISO22622 The results indicate that the QUANTUM® total ankle prosthesis met the acceptance criteria.
Pyrogen testing	The method used to make the determination that the device meets pyrogen limit specification is the Limulus Amebocyte Lysate (LAL) test in accordance with ANSI/AAMI ST72:2011: *Bacterial endotoxins – Test methods, routine monitoring and alternative to batch testing*.
CONCLUSION	**Based on the comparison of indications for use and technological characteristics and the results of the testing performed, the QUANTUM® total ankle prosthesis is substantially equivalent to the predicate devices identified in the 510(k) submission.**