April 6, 2023

In2Bones SAS
% Christine Scifert
VP QA & RA
In2Bones USA
6600 Poplar Ave, Suite 115
Memphis, Tennessee 38119

Re: K230313
Trade/Device Name: QUANTUM Patient Specific Instrumentation (PSI) System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Codes: HSN, OYK
Dated: February 3, 2023
Received: February 6, 2023

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2023.04.06 16:21:25 -04'00'

For: [Vacant]
Assistant Director
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K230313

Device Name
QUANTUM® Patient Specific Instrumentation (PSI) System

Indications for Use *(Describe)*
In2Bones PSI: In2Bones QUANTUM® Patient Specific Instrumentation (PSI) Guides for Total Ankle Replacement (TAR) is indicated as an orthopaedic instrument system to assist in the instrumentation positioning dedicated to In2Bones QUANTUM® Total Ankle Replacement implantation. In2Bones QUANTUM® PSI guides are compatible with QUANTUM® tibial tray, QUANTUM® tibial inlay, as well as standard and Flat-Cut QUANTUM® talar implants.

PSI Guides are intended for single use only. PSI Guides are manufactured in correlation with a pre-operative planning validated by the surgeon on the TAR Planning Software and assist in the positioning of the dedicated QUANTUM® instrumentation with which drillings or bone cuts will be performed. In2Bones QUANTUM® PSI guides are indicated for patient population fulfilling the QUANTUM® Total Ankle Replacement indications and for which X-rays and CT-scan images are available and compliant with imaging protocol provided by In2Bones.

TAR Planning software: The TAR Planning Software is a preoperative surgical planning software intended to be used with In2Bones QUANTUM® Patient Specific Instrumentation (PSI) Guides and QUANTUM® Total Ankle Replacement. TAR Planning Software allows the surgeon to use advanced display and positioning tools to guide the marking of bone before cutting and preview the total ankle replacement components intraoperatively, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient X-rays and imaging scans. X-rays and CT-scan are the accepted imaging modalities for these procedures.

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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**510(k) SUMMARY**
**For QUANTUM® Patient Specific Instrumentation (PSI) System**
**February 3, 2023**

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|---|---|
| Sponsor identification | In2Bones SAS<br>Sabina Ahaddad<br>28 chemin du Petit Bois<br>69130 Ecully – France<br>Phone: +33.4.72.29.26.26<br>Fax: +33.4.72.29.26.29 |
| Establishment registration number | 3010470577 |
| Date of preparation | January 9, 2023 |
| Contact person | Christine Scifert<br>In2BonesUSA<br>6000 Poplar Avenue, Suite 115<br>Memphis, TN 38119<br>Cell: 901-831-8053<br>Email: cscifert@i2b-usa.com |
| **Proprietary Name** | QUANTUM® Patient Specific Instrumentation (PSI) System |
| **Common name** | Ankle Arthroplasty Implantation System |
| **Device classification regulation** | 21 CFR 888.3110<br>Class II |
| **Device Product Code and Panel** | Orthopedic<br>HSN: Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer<br>OYK: Ankle Arthroplasty Implantation System |

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| **Device Description** | The previously cleared single use QUANTUM® Patient Specific Instrumentation (PSI) system subject of this submission consists of:<br>• QUANTUM® patient specific instrumentation (PSI) and reusable instruments:<br>- QUANTUM® patient specific tibial and talar guides;<br>- QUANTUM® reusable instruments;<br>- QUANTUM® patient specific tibial and talar bone models (*not medical devices)*;<br>• ORTHO-PLANIFY Total Ankle Replacement (TAR) planning software.<br><br>The QUANTUM® PSI system is to be used with the given QUANTUM® Total Ankle Prosthesis (K191380) and their cleared indication for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.<br><br>QUANTUM® PSI guides are single use instruments designed using the dedicated ORTHO-PLANIFY TAR planning software, in correlation with a pre-operative surgical plan validated by the surgeon. They fit the anatomy of the specific patient's distal tibia and proximal talus.<br><br>The scope of this submission is an addition of a manufacturer, slight update to dimensions and raw material for the cut guides related to the In2Bones QUANTUM® Patient Specific Instrumentation (PSI) Guides for Total Ankle Replacement (TAR) previously cleared in K211883. |
| **Predicate Devices** | Primary predicate:<br>QUANTUM® Patient Specific Instrumentation (PSI) System (K211883), In2Bones SAS<br><br>Reference predicate:<br>QUANTUM® Total Ankle Prosthesis (K191380), In2Bones SAS. |
| **Indications for use:** | In2Bones PSI: In2Bones QUANTUM® Patient Specific Instrumentation (PSI) Guides for Total Ankle Replacement (TAR) is indicated as an orthopaedic instrument system to assist in the instrumentation positioning dedicated to In2Bones QUANTUM® Total Ankle Replacement implantation. In2Bones QUANTUM® PSI guides are compatible with QUANTUM® tibial tray, QUANTUM® tibial inlay, as well as standard and Flat-Cut QUANTUM® talar implants. |

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| | PSI Guides are intended for single use only. PSI Guides are manufactured in correlation with a pre-operative planning validated by the surgeon on the TAR Planning Software and assist in the positioning of the dedicated QUANTUM® instrumentation with which drillings or bone cuts will be performed. In2Bones QUANTUM® PSI guides are indicated for patient population fulfilling the QUANTUM® Total Ankle Replacement indications and for which X-rays and CT-scan images are available and compliant with imaging protocol provided by In2Bones.<br><br>TAR Planning software: The TAR Planning Software is a preoperative surgical planning software intended to be used with In2Bones QUANTUM® Patient Specific Instrumentation (PSI) Guides and QUANTUM® Total Ankle Replacement. TAR Planning Software allows the surgeon to use advanced display and positioning tools to guide the marking of bone before cutting and preview the total ankle replacement components intraoperatively, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient X-rays and imaging scans. X-rays and CT-scan are the accepted imaging modalities for these procedures. |
| **Technological characteristics:** | The provided detailed comparison demonstrates the subject cut guides for the QUANTUM PSI system are substantially equivalent in intended use, design, operating principles, materials and performance characteristics to the predicate device cleared in K211883. The primary difference is an additional manufacturer for the cut guides. |
| **Performance Data** | Non-clinical performance data were included in the 510(k) submission. Validations associated with equipment, biocompatibility (ISO 10993) and sterilization (ISO 17665) were conducted to demonstrate that the QUANTUM PSI system is substantial equivalence to the predicate device. |
| **CONCLUSION** | **Based on the comparison of indications for use and technological characteristics and the results of the testing performed, the QUANTUM® PSI System is substantially equivalent to the predicate device identified in the 510(k) submission.** |