



April 23, 2024

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

Re: K231699

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 Code: HSN, OYK
Dated: March 20, 2024
Received: March 21, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2024.04.23 01:36:03 -04'00'

For Lixin Liu, Ph.D.
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

Indications for Use

510(k) Number (if known)

K231699

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.

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510(k) SUMMARY
For QUANTUM® Patient Specific Instrumentation (PSI) System
December 15, 2023

Sponsor identification	In2Bones SAS Stephan Epinette 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	December15, 2023
Contact person	Christine Scifert In2BonesUSA 6000 Poplar Avenue, Suite 115 Memphis, TN 38119 Cell: 901-831-8053 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 Class II
Device Product Code and Panel	Orthopedic HSN: Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer OYK: Ankle Arthroplasty Implantation System

Device Description	<p>The previously cleared single use QUANTUM[®] Patient Specific Instrumentation (PSI) system subject of this submission consists of:</p> <ul style="list-style-type: none"> • QUANTUM[®] patient specific instrumentation (PSI) and reusable instruments: <ul style="list-style-type: none"> - QUANTUM[®] patient specific tibial and talar guides; - QUANTUM[®] reusable instruments; - QUANTUM[®] patient specific tibial and talar bone models • ORTHO-PLANIFY Total Ankle Replacement (TAR) planning software (specific modification implemented in this submission).
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The QUANTUM[®] PSI Guides are patient-specific devices adapted to the patient bones anatomy and the preoperative surgical plan validated by the surgeon. QUANTUM[®] PSI guides and bone models are designed using the dedicated ORTHO-PLANIFY TAR planning software.

The QUANTUM[®] 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.

The ORTHO-PLANIFY TAR planning software involved in this submission was previously cleared under K221432.

The scope of this submission is an addition of a manufacturer for the ORTHO-PLANIFY Total Ankle Replacement (TAR) planning software related to the In2Bones QUANTUM[®] Patient Specific Instrumentation (PSI) Guides for Total Ankle Replacement (TAR) previously cleared in K211883.

Predicate Devices	<p><u>Primary predicate:</u> QUANTUM[®] Patient Specific Instrumentation (PSI) System (K211883), In2Bones SAS</p> <p><u>Reference devices:</u> QUANTUM[®] Patient Specific Instrumentation (PSI) System (K230313), In2Bones SAS</p> <p>QUANTUM[®] Total Ankle Prosthesis (K191380), In2Bones SAS</p> <p>3D-Side Customize software (K221432)</p>
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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.

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.

Note: The Indications for Use of the QUANTUM[®] Patient Specific Instrumentation (PSI) Guides and the TAR Planning Software remain unchanged compared to the primary predicate (K211883) including the QUANTUM[®] Patient Specific Instrumentation (PSI) and TAR Planning Software provided in the original submission.

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 addition of a manufacturer for the ORTHO-PLANIFY Total Ankle Replacement (TAR) planning software related to the In2Bones QUANTUM[®] Patient Specific Instrumentation (PSI) Guides for Total Ankle Replacement (TAR).

Performance Data	Non-clinical performance data were included in the 510(k) submission. Functional cadaver testing and software validations (previously provided under K221432) 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.
