March 17, 2020

Arthrex Inc.
Ivette Galmez
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

Re: K200433
Trade/Device Name: iBalance UKA Tibial Tray Implant
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: February 20, 2020
Received: February 21, 2020

Dear Ivette Galmez:

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,

for Ting Song
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200433

Device Name
iBalance UKA Tibial Tray Implant

Indications for Use *(Describe)*

The iBalance UKA Tibial Tray Implant is part of the iBalance UKA System, which is indicated for use in unicompartmental knee arthroplasty as a result of:

• Moderately disabling joint disease of the knee resulting from painful osteoarthritis or post traumatic arthritis;
• Correction of functional deformities;
• Revision of previous unsuccessful unicompartmental knee replacement or other procedure;
• As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

These components are single use only and are intended for implantation with bone cement.

When used concurrently, the Arthrex iBalance UKA and PFJ systems, create the Arthrex iBalance BiCompartmental Arthroplasty System. The Arthrex iBalance BiCompartmental Arthroplasty System is intended to be used as a multi-compartmental knee arthroplasty in patients with:

- Moderately disabling joint disease of the knee resulting from painful osteoarthritis or post traumatic arthritis;
- Correction of functional deformities;
- Revision of previous unsuccessful partial knee replacement or other procedure.

The BiCompartmental Arthroplasty System is not intended to be used as a dual-condyle or tri-compartmental knee. These components are single use only and are intended for implantation with bone cement.

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
PRAStaff@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

Date Prepared	March 17, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Ivette Galmez Senior Regulatory Affairs Specialist 1-239-643-5553, ext. 71263 Ivette.galmez@arthrex.com
Name of Device	iBalance UKA Tibial Tray Implant
Common Name	Unicompartmental Knee System
Product Code	HSX
Classification Name	21 CFR 888.3520: Knee joint femorotibial metal/polymer non-constrained, cemented prosthesis
Regulatory Class	II
Predicate Device	K060670: ACCIN UNI-Knee System K160461: Arthrex iBalance BiCompartmental Arthroplasty System
Reference Device	K171365: Arthrex Knee Systems
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for a new tibial tray model as a line extension to the Arthrex iBalance UKA System cleared under K060670.
Device Description	The proposed device is new tibial tray made of the same materials (CoCr) as the predicate. The proposed tibial tray is offered in six sizes (1-6) and available for the left-medial/right-lateral and right-medial/left-lateral compartments. The proposed device is designed for use with the cleared tibial bearing and femoral implants of the Arthrex iBalance UKA System.
Indications for Use	The iBalance UKA Tibial Tray Implant is part of the iBalance UKA System, which is indicated for use in unicompartmental knee arthroplasty as a result of: • Moderately disabling joint disease of the knee resulting from painful osteoarthritis or post traumatic arthritis; • Correction of functional deformities; • Revision of previous unsuccessful unicompartmental knee replacement or other procedure; • As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis These components are single use only and are intended for implantation with bone cement. When used concurrently, the Arthrex iBalance UKA and PFJ systems, create the Arthrex iBalance BiCompartmental Arthroplasty System. The Arthrex iBalance BiCompartmental Arthroplasty System is intended to be used as a multi-compartmental knee arthroplasty in patients with: - Moderately disabling joint disease of the knee resulting from painful osteoarthritis or post traumatic arthritis; - Correction of functional deformities; - Revision of previous unsuccessful partial knee replacement or other procedure. The BiCompartmental Arthroplasty System is not intended to be used as a dual-condyle or tri-compartmental knee. These components are single use only and are intended for implantation with bone cement.

Comparison Summary of Technological Characteristics and Modifications Proposed	The proposed device is a line extension to the predicate device. The proposed and predicate devices (K060670) have the same basic design, intended use, indications for use, shelf life and sterilization method. Proposed modifications consist of dimensional changes to the A/P length and anterior portion of the implant as well as modification of the angle of the pegs. The packaging configuration of the proposed device is the same configuration as K160461. Any differences between the proposed device and the predicate device are considered minor and do not raise questions concerning safety or effectiveness.
Performance Data	Tensile testing, Finite Element Analysis (ASTM F1800) was performed to demonstrate that the proposed device performs equivalently to the predicate. Bacterial Endotoxin test was conducted in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14 to demonstrate that the proposed device meets pyrogen limit specifications. MRI testing were conducted in accordance with FDA guidance Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment and ASTM F2182.
Conclusion	The iBalance UKA Tibial Tray Implant is substantially equivalent to the predicate device in which the basic design features and intended use are the same. The mechanical testing data demonstrates that the proposed device performance is equivalent to the predicate device for the desired indications. Any differences between the proposed device and the predicate device are considered minor and do not raise questions regarding safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate device.