July 1, 2025

Arthrex Inc.
Tiffany Mentzel
Principal Regulatory Affairs Specialist
1370 Creeksidew Blvd.
Naples, Florida 34108

Re: K251453
Trade/Device Name: Arthrex iBalance Partial Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX, KRR
Dated: May 9, 2025
Received: May 12, 2025

Dear Tiffany Mentzel:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Lixin Liu -S

Lixin Liu, PhD
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)*
K251453

Device Name
Arthrex iBalance® Partial Knee System

Indications for Use *(Describe)*
The iBalance UKA System 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.

The iBalance PFJ System is indicated for use in patellofemoral joint, (PFJ) knee arthroplasty as a result of:
• Degenerative arthritis in the distal femur and patella;
• A history of patellar dislocation or fracture;
• Failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

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 multicompartmental 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 iBalance 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.

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"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	July 1, 2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Tiffany Mentzel Title: Principal Regulatory Affairs Specialist Phone: 239-566-5833 Email: tiffany.mentzel@arthrex.com
Trade Name	Arthrex iBalance® Partial Knee System
Common Name	Knee Prosthesis
Product Code	HSX, KRR
Classification Name	21 CFR 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis 21 CFR 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Regulatory Class	II
Primary Predicate Device	K200433: iBalance UKA Tibial Tray Implant
Additional Predicate Devices	K073120: ACCIN Patellafemoral System
Reference Predicates	K171365: Arthrex Knee Systems K161060: Arthrex iBalance UKA System Vitamin E Tibial Bearing K160461: Arthrex iBalance BiCompartmental Arthroplasty System K143047: Arthrex iBalance Patella Implant, Dome K073120: ACCIN Patellafemoral System K063782: ACCIN UNI-Knee System K060670: ACCIN UNI-Knee System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the modification to the device labeling for the Arthrex iBalance Partial Knee System to include updates to the MR Conditional statement in accordance with the FDA Guidance, "Establishing Safety and compatibility of Passive Implants in the Magnetic Resonance (MR) Environment."
Device Description	The Arthrex iBalance Partial Knee System encompass the following FDA cleared devices: • Arthrex iBalance UKA System • Arthrex iBalance PFJ System • Arthrex iBalance BiCompartmental Arthroplasty System These systems are comprised of femoral, tibia and patellar components for use in knee prosthesis.
Indications for Use	The **iBalance UKA System** 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. The **iBalance PFJ System** is indicated for use in patellofemoral joint (PFJ) knee arthroplasty as a result of: • Degenerative arthritis in the distal femur and patella; • A history of patellar dislocation or fracture; • Failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists. 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 multicompartmental 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 iBalance 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.
Performance Data	Non-clinical testing and in-vivo electromagnetic simulation demonstrated that the Arthrex iBalance Partial Knee System is "MR Conditional".
Technological Comparison	The proposed Arthrex iBalance Partial Knee System and predicate devices have the same basic design, materials, and

	intended use. The only modification subject to this 510(k) is a labeling change which includes a new MR statement.
Conclusion	The Arthrex iBalance Partial Knee System is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device do not raise different questions of 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.