



November 7, 2017

Arthrex Inc.
David L. Rogers
Project Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K171365

Trade/Device Name: Arthrex Knee Systems
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, HSX, KRR
Dated: October 3, 2017
Received: October 11, 2017

Dear Mr. Rogers:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K171365

Device Name

Arthrex iBalance BiCompartmental Arthroplasty System

Indications for Use (Describe)

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (*if known*)

K171365

Device Name

Arthrex iBalance PFJ

Indications for Use (*Describe*)

The Arthrex iBalance PFJ components are intended for use in patellofemoral knee arthroplasty in patients with:

- 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.

Type of Use (*Select one or both, as applicable*)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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See PRA Statement below.

Indications for Use

510(k) Number (if known)

K171365

Device Name

Arthrex iBalance TKA System

Indications for Use (Describe)

The Arthrex iBalance TKA System is indicated for use in individuals undergoing surgery for:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Revisions of previous unsuccessful knee replacement or other procedure.

Additional indications for posteriorly stabilized components:

- Ligamentous instability requiring implant bearing surfaces with increased constraint;
- Absent or non-functioning posterior cruciate ligament.

These devices are single use only and are intended for implantation with bone cement, with the exception of porous coated femoral components which can be used cemented or uncemented (biological fixation).

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number (if known)

K171365

Device Name

Arthrex iBalance UKA System

Indications for Use (Describe)

Arthrex iBalance UKA System is intended 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.

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)

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510(k) Summary or 510(k) Statement

Date Prepared	May 5, 2017
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	David L Rogers Project Manager, Regulatory Affairs 1-239-643-5553, ext. 71924 david.rogers@arthrex.com
Name of Device	Arthrex Knee Systems
Common Name	Knee Prosthesis
Product Code	MBH, HSX, KRR
Classification Name	21 CFR 888.3565: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis 21 CFR 888.3560: Prosthesis, Knee, Patellofermorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer 21 CFR 888.3520: Prosthesis, Knee, Femorotibial, Non-Constrained, Metal/Polymer
Regulatory Class	II
Predicate Device	K161060: Arthrex iBalance UKA System Vitamin E Tibial Bearing K160461: Arthrex iBalance BiCompartmental Arthroplasty System K153586: Arthrex iBalance TKA System K152382: Arthrex iBalance TKA System K152252: Arthrex iBalance TKA System K143047: Arthrex iBalance Patella Implant, Dome K133854: Arthrex iBalance TKA System K073120: ACCIN Patellafemoral System K063782: ACCIN UNI-Knee System K060670: ACCIN UNI-Knee System
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the modification to the device labeling for the Arthrex Knee Systems to include 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 Knee Systems encompass the following FDA cleared devices: • Arthrex iBalance TKA System • Arthrex iBalance UKA System • Arthrex iBalance PFJ • Arthrex iBalance BiCompartmental Arthroplasty System These systems are comprised of femoral, tibia, and patellar components for use in knee prosthesis.
Indications for Use	The Arthrex iBalance TKA System is indicated for use in individuals undergoing surgery for: • Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis; • Post-traumatic loss of knee joint configuration and function • Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;

- Revisions of previous unsuccessful knee replacement or other procedure.

Additional indications for posteriorly stabilized components:

- Ligamentous instability requiring implant bearing surfaces with increased constraint;
- Absent or non-functioning posterior cruciate ligament.

These devices are single use only and are intended for implantation with bone cement, with the exception of porous coated femoral components which can be used cemented or uncemented (biological fixation).

Arthrex **iBalance UKA System** is intended 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 **Arthrex iBalance PFJ** components are intended for use in patellofemoral knee arthroplasty in patients with:

- 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 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.

Performance Data

Non-clinical testing and in-vivo electromagnetic simulation per the FDA Guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", demonstrated that the Arthrex Knee Systems are "MR Conditional".

Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.

Conclusion

The Arthrex Knee Systems are 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 are considered minor and do not raise questions concerning 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.