DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 15, 2016

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

Re: K161060
Trade/Device Name: Arthrex iBalance UKA System Vitamin E Tibial Bearing
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX, OIY
Dated: November 22, 2016
Received: November 23, 2016

Dear David 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	December 5, 2016
Manufacturer/Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	David L Rogers Project Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71924 Fax: 239/598.5508 Email: david.rogers@arthrex.com
Trade Name	***Arthrex iBalance UKA System Vitamin E Tibial Bearing***
Common Name	Unicompartmental Knee System
Primary Product Code - Classification Name CFR	HSX Prosthesis, Knee, Femorotibial, Non-Constrained, Metal/Polymer 21 CFR 888.3520
Secondary Product Code - Classification Name CFR	OIY Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive 21 CFR 888.3560
Predicate Device	K060670: Accin UNI-Knee System
Reference Predicate Device	K153586: Arthrex iBalance TKA System
Purpose of Submission	This special 510(k) premarket notification is submitted to obtain clearance for a line extension to the **Arthrex iBalance UKA System**, which would add a Vitamin E blended UHMWPE tibial bearing component.
Device Description	The tibial bearing is made from Vitamin E blended UHMWPE and is available in 6 sizes, ranging from 8-14mm in thickness. The design is symmetrical and may be used for either the medial or lateral compartment of the left or right knee in unicompartmental arthroplasty as part of the **Arthrex iBalance UKA System**.

Indications for Use	***Arthrex iBalance UKA System* components** are 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.
Substantial Equivalence Summary	The proposed **Arthrex iBalance UKA System Vitamin E Tibial Bearing** is similar to the predicate device, in which the basic design features and intended uses are the same. The Vitamin E material used for the tibial bearing has been previously cleared under K153586. Shear interlock testing was conducted on the proposed Vitamin E blended UHMWPE tibial bearing to demonstrate that the maximum moment force meets the acceptance criteria established in the predicate 510(k). Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the **Arthrex iBalance UKA System Vitamin E Tibial Bearing** is substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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

510(k) Number *(if known)*

K161060

Device Name

Arthex iBalance UKA System Vitamin E Tibial Bearing

Indications for Use *(Describe)*

The Arthrex iBalance UKA System components are 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.