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

April 12, 2016

Arthrex, Incorporated
Courtney Smith
Regulatory Affairs Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K160461
Trade/Device Name: Arthrex iBalance BiCompartmental Arthroplasty System
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRR, HSX
Dated: February 12, 2016
Received: February 19, 2016

Dear Courtney Smith:

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 Parts 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" (21CFR 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

2.1 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	April 6, 2016
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Regulatory Affairs Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: courtney.smith@arthrex.com
Trade Name	***iBalance BiCompartmental Arthroplasty System***
Common Name	Knee Prosthesis
Product Code -Classification Name CFR	**KRR** – Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis, CFR 888.3540 **HSX** – Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal Polymer CFR 888.3520
Predicate Device	K073120: ACCIN Patellofemoral System K063782, K060670: ACCIN UNI-Knee System K090763: Mako Restoris MCK K052917: Stryker Compartmental Knee System
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain FDA clearance for use of the Arthrex iBalance UKA system in conjunction with the Arthrex iBalance PFJ System to create the Arthrex iBalance BiCompartmental Arthroplasty System
Device Description	The ***Arthrex iBalance BiCompartmental Arthroplasty System*** is comprised of a unicompartmental implant system (Arthrex iBalance UKA) and a patellofemoral implant system (Arthrex iBalance PFJ). The Arthrex iBalance UKA and Arthrex iBalance PFJ systems may be

	used in conjunction to create a bicompartmental patellofemorotibial replacement for the medial or lateral side of the knee.
Intended Use	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
Substantial Equivalence Summary	The ***iBalance BiCompartmental Arthroplasty system*** is substantially equivalent to the predicate devices in which the basic features and intended uses are the same. Any differences between the ***iBalance BiCompartmental Arthroplasty system*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The proposed devices are substantially equivalent to the predicate devices in regards to its intended use, design, size ranges, and materials. The submitted biomechanical testing data demonstrated the system worked well and the two systems did not impinge on one another. No further instrumentation beyond the existing devices cleared with the original systems was required to perform the procedure. Mechanical data is unchanged from the original clearances; no further mechanical testing is necessary to demonstrate that the ***iBalance BiCompartmental Arthroplasty System*** is adequate for its intended use. Clinical data and conclusions are not needed for this device. Based on the indication for use, technological

	characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the ***iBalance BiCompartmental Arthroplasty system*** is substantially equivalent to currently marketed predicate devices.

2.1 INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K160461

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*