



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

Custom Orthopaedic Solutions  
Mr. Keith Grafmeyer  
Product Engineer  
10000 Cedar Avenue  
Cleveland, Ohio 44106

October 5, 2015

Re: K151500

Trade/Device Name: Arthrex Glenoid Intelligent Reusable Instrument System  
Regulation Number: 21 CFR 888.3660  
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: Class II  
Product Code: KWS  
Dated: September 11, 2015  
Received: September 11, 2015

Dear Mr. Grafmeyer:

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

Page 2 - Mr. Keith Grafmeyer

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

## Indications for Use

510(k) Number (if known)

K151500

Device Name

Arthrex Glenoid Intelligent Reusable Instrument System

Indications for Use (Describe)

The Glenoid Intelligent Reusable Instrument System ("Glenoid IRIS") is a patient specific manual instrument system intended to facilitate preoperative planning and intraoperative placement of the central glenoid guide pin used in the preparation of the glenoid in total shoulder systems that utilize a central guide pin for preparing the glenoid to receive the glenoid implant.

The Arthrex Glenoid IRIS is indicated for use with the Arthrex Univers II or Arthrex Univers Apex, Keeled or Pegged Glenoid components as well as the Univers Revers Baseplate component.

The indications for use of the Arthrex shoulder systems with which the Arthrex Glenoid IRIS is intended to be used are the same as those described in the labeling for these shoulder systems.

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.

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**510(k) Summary**

**510(k) SPONSOR / MANUFACTURER:** Custom Orthopaedic Solutions, Inc.  
A subsidiary of Cleveland Clinic  
10000 Cedar Avenue  
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**TRADE NAME:** Arthrex Glenoid Intelligent Reusable  
Instrument System (Arthrex Glenoid IRIS)

**DATE PREPARED:** 28-May-2015

**COMMON NAMES:** Total shoulder replacement instruments

<b>Product</b>	<b>Product Code</b>	<b>Regulation and Classification Name</b>	<b>Device Class</b>
<b>Arthrex Glenoid Intelligent Reusable Instrument System (Arthrex Glenoid IRIS)</b>	<b>KWS, PHX</b>	<b>21 CFR 888.3660 Shoulder Joint Metal/Polymer, Semi-Constrained Cemented Prosthesis</b>	<b>II</b>

**PREDICATE DEVICES:**  
Glenoid Intelligent Reusable Instrument System (Glenoid IRIS) (K142072)

**DEVICE DESCRIPTION:**  
The Glenoid Intelligent Reusable Instrument System (“Glenoid IRIS”) is a patient specific manual instrument system intended to facilitate preoperative planning and intraoperative placement of the central glenoid guide pin used in the preparation of the glenoid in total shoulder systems that utilize a central guide pin for preparing the glenoid to receive the glenoid implant.

The Arthrex Glenoid Intelligent Reusable Instrument System described in this submission

is identical to the Glenoid IRIS cleared in K142072, except for the following differences:

- The Glenoid IRIS for the K142072 clearance was indicated for use with the DePuy family of shoulder replacement systems. The subject device is indicated for use with the Arthrex family of glenoid components, which includes:
  - o Univers™ II and Univers™ Apex Keeled Glenoid,
  - o Univers™ II and Univers™ Apex Pegged Glenoid,
  - o Univers Revers™ Baseplate.
  
- The DePuy implant models in the OrthoVis planning software have been replaced with Arthrex implant models.
  
- The OrthoVis User's Manual and User Training Manual contain references to the implant company's instructions as to how their glenoid implants should be placed in patients. For this current submission, the User's Manual and User Training Manual have been changed to reflect the approved labeling for how Arthrex instructs these implants to be placed in patients.

All other elements of the K142072 clearance are identical to this submission.

#### **INTENDED USE AND INDICATIONS:**

The Glenoid Intelligent Reusable Instrument System ("Glenoid IRIS") is a patient specific manual instrument system intended to facilitate preoperative planning and intraoperative placement of the central glenoid guide pin used in the preparation of the glenoid in total shoulder systems that utilize a central guide pin for preparing the glenoid to receive the glenoid implant.

The Arthrex Glenoid IRIS is indicated for use with the Arthrex Univers™ II or Arthrex Univers™ Apex, Keeled or Pegged Glenoid components as well as the Univers Revers™ Baseplate component.

The indications for use of the Arthrex shoulder systems with which the Arthrex Glenoid IRIS is intended to be used are the same as those described in the labeling for these shoulder systems.

#### **BASIS OF SUBSTANTIAL EQUIVALENCE:**

The "Arthrex Glenoid IRIS" is substantially equivalent to the Glenoid Intelligent Reusable Instrument System (Glenoid IRIS) described in K142072 because it is the same system with no modifications, other than the change from one shoulder implant system to another, similar shoulder implant system. Both the DePuy and Arthrex shoulder implant systems use a glenoid center pin to guide the subsequent preparation of the glenoid surface prior to implant placement.

#### **Non-Clinical Testing:**

The following testing was performed to demonstrate substantial equivalency of the Arthrex Glenoid IRIS to the predicate device in K142072.

- Verification and Validation of the OrthoVis software modules affected by the change from DePuy to Arthrex implants, and confirmation that those changes had no other effects on any other parts of OrthoVis.
- OrthoVis inter- and intra-user testing, to confirm that OrthoVis users can accurately place the Arthrex implants according to the Arthrex approved labeling for placement of their implants.

**Clinical Testing:**

Clinical testing was not necessary to determine substantial equivalence between the modified Glenoid IRIS and the predicate Glenoid IRIS (K142072).