



Food and Drug Administration
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Custom Orthopaedic Solutions, Incorporated
Mr. Keith Grafmeyer
Project Manager
10000 Cedar Avenue
Cleveland, Ohio 44106

February 19, 2016

Re: K153215

Trade/Device Name: SmartBase for Arthrex Glenoid IRIS
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, PHX
Dated: January 29, 2016
Received: February 2, 2016

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 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

Indications for Use

510(k) Number (if known)

K153215

Device Name

SmartBase for Arthrex Glenoid IRIS

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
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TRADE NAME: SmartBase for Arthrex Glenoid IRIS

COMMON NAMES: Total shoulder replacement instruments

Product	Product Code	Regulation and Classification Name	Device Class
SmartBase for Glenoid IRIS	KWS, PHX	21 CFR 888.3660 Shoulder, semi-constrained metal / polymer, cemented	II

PREDICATE DEVICES:

Arthrex Glenoid Intelligent Reusable Instrument System (Arthrex Glenoid IRIS) (K151500)

DEVICE DESCRIPTION:

The SmartBase is a reusable instrument that allows the IRI device from the Arthrex Glenoid IRIS system (K151500) to be set according to prescribed lengths and heights for a specific patient's glenoid anatomy. The IRI leg lengths and their respective heights are determined in the OrthoVis software which is a part of the Arthrex Glenoid IRIS system. Along with the IRI leg lengths for each IRI slot and their respective heights, images of where the IRI was planned to sit on the patient's glenoid for the prescribed leg lengths and heights are given.

Loading the IRI device according to the prescribed lengths, setting the height of each IRI leg according to the prescribed SmartBase ruler heights, and then placing the IRI on the glenoid according to the preoperative plan images allows the IRI to transfer the guide pin

for the surgeon-approved, preoperatively-planned glenoid implant trajectory to the patient in the OR. It provides the same function as the SmartBone (setting the IRI device), which was previously cleared in the predicate, K151500.

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 SmartBase instrument for the Arthrex Glenoid IRIS system is substantially equivalent to the SmartBone—Pin Trajectory instrument in the Arthrex Glenoid IRIS system (K151500) in terms of intended use, function, biocompatibility, sterility, safety, and effectiveness/performance.

Non-Clinical Testing

The following testing was performed to demonstrate substantial equivalency of the SmartBase instrument to the SmartBone—Pin Trajectory instrument of the predicate device in K151500.

- SmartBase vs. SmartBone End Result Comparison Study
- Sterilization/Cleaning Validation of the SmartBase device in the modified Arthrex Glenoid IRIS tray

Clinical Testing

Clinical testing was not necessary to determine substantial equivalence between the SmartBase and the SmartBone instrument (K151500).

SmartBase vs. SmartBone Comparison Study

Results of the SmartBase vs. SmartBone study found that there is no significant difference between using the SmartBase or the SmartBone—Pin Trajectory instrument in placing the glenoid guide pin. Results also found that there was no significant error in achieving the planned IRI leg heights with the SmartBase device.

Biocompatibility

The SmartBase device is made of an anodized aluminum base, passivated 316 stainless steel SmartBase Rulers and Central Pillar. The IRI Device only contacts the SmartBase at the rulers and central pillar. The 316 stainless steel used in the rulers and central pillar is in conformance with ISO 16061: Instrumentation for use in association with non-active surgical implants – General requirements. Brass thumb screws are used for locking the SmartBase rulers in place and do not come in contact with the IRI device.

The portions of the SmartBase device that contact the IRI and hence have a potential to indirectly contact the patient are all 316 stainless steel. According to the FDA's Guidance on the Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", the subject device (SmartBase) does not require further biocompatibility testing because the parts that may indirectly contact the patient are composed of a commonly used biocompatible alloy: 316 stainless steel. Therefore, there is no change in biocompatibility between the subject (SmartBase) and predicate (SmartBone) device.

Cleaning/Sterilization Validation

The Arthrex Glenoid IRIS Instrument Tray was modified to allow additional brackets to hold the disassembled SmartBase rulers, brass thumb screws, and central pillar. The core of the SmartBase was designed to sit in the same bracket as the SmartBone.

Cleaning and Sterilization Validation was performed on the SmartBase device in a fully loaded Arthrex Glenoid IRIS Instrument tray.