February 10, 2017

Dear Keith 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
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,

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)
K162697

Device Name
Arthrex Glenoid Intelligent Reusable Instrument System (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 and Arthrex Univers Apex, Keel or Pegged Glenoid components, the Vault Lock Glenoid Component, 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)

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTAFF@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*
Indications for Use

510(k) Number *(if known)*
K162697

Device Name
Arthrex OrthoVis Preoperative Plan

Indications for Use *(Describe)*
The Arthrex OrthoVis Preoperative Plan is a preoperative plan created via the OrthoVis software that facilitates accurate preoperative planning and intraoperative placement of the glenoid component in total shoulder replacement.

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

The indications for use of the Arthrex shoulder systems with which the Arthrex OrthoVis Preoperative Plan 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)*

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)
K162697

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 and Arthrex Univers Apex, Keeled or Pegged Glenoid components, the Vault Lock Glenoid Component, 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)

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Indications for Use

510(k) Number (if known)
K162697

Device Name
ArthrexVIP Web Portal

Indications for Use (Describe)
The ArthrexVIP Web Portal is intended for use as a software interface and for the transfer of imaging information from a medical scanner such as a CT scanner. It is also intended as software for displaying/editing implant placement and surgical treatment options that were generated in the OrthoVis Desktop Software by trained COS technicians. The ArthrexVIP Web Portal is intended for use with the Arthrex Glenoid Intelligent Reusable Instrument System (Arthrex Glenoid IRIS) and with the Arthrex OrthoVis Preoperative Plan. It is indicated for use with the following glenoid implant lines: Arthrex Univers II and Arthrex Univers Apex, Keel or Pegged Glenoid components, the Vault Lock Glenoid Component, as well as the Univers Revers Baseplate component.

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.
7100 Euclid Ave
Ste 180
Cleveland OH, 44103

### CONTACT PERSON:
Keith Grafmeyer  
*Project/Regulatory Manager*
Custom Orthopaedic Solutions  
Tel: (216) 800-5905 Ext. 102  
Email: kgrafmeyer@customorthopaedics.com

### TRADE NAMES:
Arthrex Glenoid Intelligent Reusable Instrument System, Arthrex OrthoVis Preoperative Plan, SmartBase for Arthrex Glenoid IRIS, ArthrexVIP Web Portal

### DATE PREPARED:
6-Jan-17

### COMMON NAMES:
Total shoulder replacement system / instruments, Preoperative planning software/plan, Preoperative Planning Web Software

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Code</th>
<th>Regulation and Classification Name</th>
<th>Device Class</th>
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<tr>
<td>K151500: Arthrex Glenoid Intelligent Reusable Instrument System (Arthrex Glenoid IRIS)</td>
<td>KWS, PHX</td>
<td>21 CFR 888.3660 Shoulder Joint Metal/Polymer, Semi-Constrained Cemented Prosthesis</td>
<td>II</td>
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<tr>
<td>K151568: Arthrex OrthoVis Preoperative Plan</td>
<td>LLZ</td>
<td>21 CFR 892.2050 Picture Archiving &amp; Communications System</td>
<td>II</td>
</tr>
<tr>
<td>K153612: ArthrexVIP Web Portal</td>
<td>LLZ</td>
<td>21 CFR 892.2050 Picture Archiving &amp; Communications System</td>
<td>II</td>
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K153215: SmartBase for Arthrex Glenoid IRIS

21 CFR 888.3660
Shoulder Joint Metal/Polymer,
Semi-Constrained Cemented Prosthesis

<table>
<thead>
<tr>
<th>Subject Device</th>
<th>Corresponding Predicate Device(s)</th>
</tr>
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<tr>
<td>K151500</td>
<td>K142072: Glenoid Intelligent Reusable Instrument System (Glenoid IRIS)</td>
</tr>
<tr>
<td>K151568</td>
<td>K133367: OrthoVis Preoperative Plan</td>
</tr>
<tr>
<td>K153215</td>
<td>K151500: Arthrex Intelligent Reusable Instrument System (Arthrex Glenoid IRIS)</td>
</tr>
</tbody>
</table>

DEVICE DESCRIPTION:
The Glenoid IRIS is an instrument system intended for use in total shoulder replacement to facilitate preoperative planning and intraoperative placement of the glenoid implant component.

This bundled submission contains four traditional 510(k) submissions associated with Arthrex Glenoid IRIS. All of the submissions correspond to components of the system that are intended for use together to place the guide pin, and subsequently the glenoid implant, in a total shoulder replacement surgery. All of the components (subject devices in the bundled submissions) of Arthrex Glenoid IRIS are indicated for use with the Arthrex lines of Glenoid implants. We would now like to add the Arthrex Vault Lock glenoid implant to this list of compatible/indicated implant systems.

INTENDED USE AND INDICATIONS:
K151500
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 and Arthrex Univers Apex, Keeled or Pegged Glenoid components, the Vault Lock Glenoid Component, as well as the Univers Revers Baseplate component.
The indications for use of the Arthrex shoulder systems with which the Arthex Glenoid IRIS is intended to be used are the same as those described in the labeling for these shoulder systems.

K151568
The Arthrex OrthoVis Preoperative Plan is a preoperative plan created via the OrthoVis software that facilitates accurate preoperative planning and intraoperative placement of the glenoid component in total shoulder replacement.

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

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

K153612
The ArthrexVIP Web Portal is intended for use as a software interface and for the transfer of imaging information from a medical scanner such as a CT scanner. It is also intended as software for displaying/editing implant placement and surgical treatment options that were generated in the OrthoVis Desktop Software by trained COS technicians. The ArthrexVIP Web Portal is intended for use with the Arthrex Glenoid Intelligent Reusable Instrument System (Arthrex Glenoid IRIS) and with the Arthrex OrthoVis Preoperative Plan. It is indicated for use with the following glenoid implant lines: Arthrex Univers II and Arthrex Univers Apex, Keeled or Pegged Glenoid components, the Vault Lock Glenoid Component, as well as the Univers Revers Baseplate component.

K153215
Identical to K151500 above.

BASIS OF SUBSTANTIAL EQUIVALENCE:
All of the devices in this bundled submission are still substantially equivalent to their predicates because their underlying scientific characteristics have not changed. The only change to these devices is the addition of Arthrex Vault Lock as an indicated glenoid implant line. The CAD models have been added to the templating software and the design has not changed otherwise.

SUMMARY OF VERIFICATION/VALIDATION TESTING
- Verified with manufacturer (Arthrex) that new implant should be placed by COS technicians, using the same protocol as the other anatomic implants previously cleared with the bundled devices.
• Manual software verification and validation testing of Arthrex OrthoVis Desktop Software
• Automatic verification and validation testing of Arthrex VIP Web Software
• Dimensional validation of implants in OrthoVis Desktop Software