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

March 15, 2016

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

Re: K153612
Trade/Device Name: ArthrexVIP Web Portal
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, KWS, PHX
Dated: December 7, 2015
Received: December 17, 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 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,

Lori A. Wiggins -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
~~N/A~~ K153612

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 Apex, Arthrex Univers II, and Arthrex Univers Revers.

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.
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TRADE NAME: ArthrexVIP Web Portal

DATE PREPARED: 07-Dec-2015

COMMON NAMES: Image processing system and preoperative software for simulating / evaluating implant placement and surgical treatment options

Product	Product Code	Regulation and Classification Name	Device Class
ArthrexVIP Web Portal	**LLZ**	**21 CFR 892.2050 Picture Archiving and Communications System**	**II**
ArthrexVIP Web Portal	**KWS**	**21 CFR 888.3660 Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented**	**II**
ArthrexVIP Web Portal	**PHX**	**21 CFR 888.3660 Shoulder Prosthesis, Reverse Configuration**	**II**

Predicate Devices:
K151501: OrthoVis Web Portal
K151568: Arthrex OrthoVis Preoperative Plan
K151500: Arthrex Glenoid Intelligent Reusable Instrument System (Arthrex Glenoid IRIS)

Device Description:
The ArthrexVIP Web Portal is composed of software intended for use to facilitate upload of medical

images, preoperative planning, and plan approval of placement and orientation of total shoulder joint replacement components. Each surgeon user's uploaded images are associated with specific cases and associated with that surgeon's profile. Uploaded images can be downloaded from the portal by COS technicians and used to create preoperative plans (see 510(k) K151568) in the OrthoVis Desktop Software. The surgeon user is then able to login to the ArthrexVIP Web Portal to review the preoperative plan and either approve or modify the location and/or orientation of the joint replacement component. The approved plan is then downloaded by COS technicians for product production (see 510(k) K151500 and K151568) as part of the Arthrex Glenoid IRIS device.

Intended Use and Indications:

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 Apex, Arthrex Univers II, and Arthrex Univers Revers.

Basis of Substantial Equivalence:

The ArthrexVIP Web Portal has the same intended use and indications for use as the OrthoVis Web Portal (K151501), with the exception of ArthrexVIP being indicated for use solely with the Arthrex line of shoulder arthroplasty implants.

The subject device is a version of the predicate device with changes to the following:

- Measurement Features
- Viewer Controls
- Implant Controls and Options
- Organization of information
- User Interface (UI)

Non-Clinical Testing

The following testing was performed to demonstrate substantial equivalency of the ArthrexVIP Web Portal to the OrthoVis Web Portal:

- Software verification and validation
- Regression Testing
- Unit Testing
- Code reviews and checks
- Integration Testing
- Dimensional Validation (performed on predicate device and code has not changed for the subject device)

Clinical Testing

Clinical testing was not necessary to determine substantial equivalence between to the predicate.