



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Custom Orthopaedic Solutions, Inc.  
% Mr. Peter O'Neill  
President  
10000 Cedar Avenue  
CLEVELAND OH 44106

July 31, 2015

Re: K151568  
Trade/Device Name: Arthrex OrthoVis Preoperative Plan  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: July 1, 2015  
Received: July 8, 2015

Dear Mr. O'Neill:

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 yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

Robert Ochs, Ph.D.  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151568

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 Preoperative Plan is indicated for use in planning the central glenoid guide pin for the Arthrex Univers™ II and Univers™ Apex Keeled glenoid component, Univers™ II and Univers™ Apex Pegged glenoid component, and the Univers Revers™ Baseplate.

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)

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  
Cleveland, Ohio 44106

**CONTACT PERSON:** Peter O’Neill  
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**DATE PREPARED:** 1-June-2015

**TRADE NAME:** Arthrex OrthoVis Preoperative Plan

**COMMON NAMES:** Preoperative Planning tool

<b>Product</b>	<b>Product Code</b>	<b>Regulation and Classification Name</b>	<b>Device Class</b>
<b>Arthrex OrthoVis Preoperative Plan</b>	<b>LLZ</b>	<b>21 CFR 892.2050 Picture Archiving &amp; Communications System</b>	<b>II</b>

### **PREDICATE DEVICES:**

Custom Orthopaedic Solutions OrthoVis Preoperative Plan (K133367)

### **DEVICE DESCRIPTION:**

The Arthrex OrthoVis Preoperative Plan is a preoperative plan document that is created in the OrthoVis software. A patient CT scan is loaded into the OrthoVis software and the desired bony anatomy can be separated and segmented with OrthoVis tools, allowing extracted and segmented bones (e.g., scapula, humerus) to be virtually implanted with shoulder replacement implants.

This 510(k) submission is identical to the OrthoVis Preoperative Plan (K133367) submission and clearance with the exception of the following modifications:

- The intended use of the OrthoVis Preoperative Plan for the K133367 clearance was for the Depuy family of glenoid components (Global APG, Global StepTech, and Delta Xtend). These components have now been replaced in the OrthoVis software with the Arthrex family of glenoid components which include:
  - o Univers™ II and Univers™ Apex Keeled Glenoid,
  - o Univers™ II and Univers™ Apex Pegged Glenoid,
  - o Univers Revers™ Baseplate.

OrthoVis can produce a preoperative plan document (.pdf file) that contains text, images, and in electronic format, a rotatable 3D model(s) of the implanted component and bone. This preoperative plan document is labeled, via a watermark, as unapproved until the ordering surgeon approves the plan, at which point such labeling is removed and the final plan is provided to the ordering surgeon.

**INTENDED USE AND INDICATIONS:**

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 Preoperative Plan is indicated for use in planning the central glenoid guide pin for the Arthrex Univers™ II and Univers™ Apex Keeled glenoid component, Univers™ II and Univers™ Apex Pegged glenoid component, and the Univers Revers™ Baseplate.

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.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The Arthrex OrthoVis Preoperative Plan is substantially equivalent to 510(k) K133367 because the indications for use and intended use are identical with the exception of replacing the Depuy family of glenoid components with the Arthrex family of glenoid components in the OrthoVis software. Both the Depuy and Arthrex shoulder implant systems use a central guide pin to guide the subsequent preparation of the glenoid surface prior to implant placement. Both the subject device and predicate device aim to improve central guide pin placement accuracy by providing a surgeon with a preoperative plan in the form of a PDF document.

**Non-Clinical Testing**

The following testing was performed to demonstrate substantial equivalency of the Arthrex OrthoVis Preoperative Plan to the predicate device.

- Software verification and validation
- Inter and Intra User Surgical Planning Comparison Study