Arthrex Inc.
Heli Chambi Infantas
Sr. Regulatory Affairs Associate
1370 Creekside Blvd
NAPLES, FL 34108

April 30, 2020

Re: K193523
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
Dated: March 28, 2020
Received: March 31, 2020

Dear Heli Chambi Infantas:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael C. Owens
Acting Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193523

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 Arthrex 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 and Modular Glenoid System (MGS) Baseplate components.

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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K193523

510(k) Summary

510(k) SPONSOR / MANUFACTURER: Arthrex Inc.
1370 Creekside Blvd
Naples, FL 34108

CONTACT PERSON: **Heli F. Chambi Infantas**
Sr. Regulatory Affairs Associate
1-239-598-4302, ext. 73187
Heli.Chambiinfantas@arthrex.com

TRADE NAME: ArthrexVIP Web Portal

DATE PREPARED: 16-Dec-2019

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**

Predicate Devices:
K162697: ArthrexVIP Web Portal

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 Arthrex 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 Arthrex 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 Arthrex 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 and Modular Glenoid System (MGS) Baseplate components.

Basis of Substantial Equivalence:

The modified ArthrexVIP Web Portal has the same intended use and indications for use as the predicate ArthrexVIP Web Portal (K162697) with the exception of "COS technicians" now being "Arthrex technicians" to reflect the change in manufacturer from Custom Orthopaedic Solutions (COS) to Arthrex and the addition of the Modular Glenoid System baseplate to the indicated glenoid implant lines.

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

- Addition of backside seating feature
- Addition of the Univers Revers Modular Glenoid System (MGS) implant models
- Addition of the Univers Revers Universal Glenoid (UG) implant models
- Addition of the glenosphere and inlay implant models compatible with MGS and UG
- Addition of glenoid bone preparation instrument models for visualization
- Addition of the Univers Revers screw trajectory models for visualization

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 verification

Clinical Testing

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