Arthrex Inc.
Troy Brooks
Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

June 22, 2023

Re: K230904
Trade/Device Name: Arthrex Virtual Implant Positioning (VIP) System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: QHE
Dated: April 19, 2023
Received: April 21, 2023

Dear Troy Brooks:

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2023.06.22 13:15:00 -04'00'

Farzana Sharmin, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230904

Device Name

Arthrex Virtual Implant Positioning (VIP) System - VIP Web Portal

Indications for Use *(Describe)*

The VIP 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 VIP Web Portal is intended for use with the VIP glenoid instrumentation and with the OrthoVis preoperative plan. It is indicated for use with the following implant lines: Univers™ II and Univers™ Apex total shoulder systems, keeled or pegged glenoid components, the Univers VaultLock® glenoid component, as well as the Univers Revers™ baseplate component (Universal Glenoid), Univers Revers™ modular glenoid system (MGS) baseplates, and Arthrex humeral implants compatible with these implant lines.

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.

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

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

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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230904

Device Name

Arthrex Virtual Implant Positioning (VIP) System - OrthoVis Preoperative Plan

Indications for Use *(Describe)*

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

The VIP Glenoid Targeter is indicated for use with the Univers™ II and Univers™ Apex total shoulder systems, keeled or pegged glenoid components, the Univers VaultLock® glenoid component, as well as the Univers Revers™ baseplate component (Universal Glenoid) and Univers Revers™ modular glenoid system (MGS) baseplates.

The VIP Glenoid Reamer is indicated for use with the Univers VaultLock® glenoid component and the Univers Revers™ modular glenoid system (MGS) baseplates.

The indications for use of the Arthrex shoulder systems with which the 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.

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

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

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."

510(k) Summary

Date Prepared	June 21, 2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Troy Brooks, RAC Manager, Regulatory Affairs 1-239-643-5553 Troy.Brooks@Arthrex.com
Name of Device	Arthrex Virtual Implant Positioning (VIP) System
Common Name	Preoperative Planning Software
Product Code	QHE
Classification Name	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class	II
Primary Predicate	K222007: Arthrex Virtual Implant Positioning (VIP) System software (VIP Web Portal and OrthoVis Preoperative Plan)
Additional Predicate	K213546: Blue Ortho ExactechGPS Total Shoulder Application/Equinoxe Planning Software
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for new preoperative planning of humeral components in total shoulder arthroplasty and associated expanded indications for use for the existing Arthrex Virtual Implant Positioning (VIP) System software (VIP Web Portal and OrthoVis Preoperative Plan) cleared under K222007.
Device Description	Arthrex Virtual Implant Positioning (VIP) System software comprises VIP Web Portal software and OrthoVis Preoperative Plan software. The VIP Web Portal is web-based software intended for use to facilitate the upload of medical images, preoperative planning, and plan approval of placement and orientation of total joint replacement components. Each surgeon user's uploaded images are grouped into cases and associated with that user's profile. Uploaded images can be downloaded from the VIP Web Portal by Arthrex technicians and used to create preoperative plans in OrthoVis (a desktop application). Once created, the preoperative plans are uploaded back to the VIP Web Portal, where the surgeon user is then able to login and review the preoperative plan. Subsequently, the surgeon user may either approve the plan, or modify the type, size, location and/or orientation of the joint replacement component and then approve the plan. The approved plan is then made available for download by the surgeon user.
Indications for Use	The VIP 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 VIP Web Portal is intended for use with the VIP glenoid instrumentation and with the OrthoVis preoperative plan. It is indicated for use with the following implant lines: Univers™ II and Univers™ Apex total shoulder systems, keeled or pegged glenoid components, the Univers VaultLock® glenoid component, as well as the Univers Revers™ baseplate component (Universal Glenoid), Univers Revers™ modular glenoid system (MGS) baseplates, and Arthrex humeral implants compatible with these implant lines. The OrthoVis Preoperative Plan is a preoperative plan created via the OrthoVis software that facilitates accurate preoperative planning of glenoid and humeral components in total shoulder replacement, and intraoperative placement of the glenoid component in total shoulder replacement. The VIP Glenoid Targeter is indicated for use with the Univers™ II and Univers™ Apex total shoulder systems, keeled or pegged glenoid components, the Univers VaultLock® glenoid component, as well as the Univers Revers™ baseplate component (Universal Glenoid) and Univers Revers™ modular glenoid system (MGS) baseplates.

Indications for Use (continued)	The VIP Glenoid Reamer is indicated for use with the Univers VaultLock® glenoid component and the Univers Revers™ modular glenoid system (MGS) baseplates. The indications for use of the Arthrex shoulder systems with which the OrthoVis Preoperative Plan is intended to be used are the same as those described in the labeling for these shoulder systems.
Summary of Technological Characteristics	As compared to the primary predicate device used for preoperative planning of glenoid components, the subject device now includes preoperative planning of both glenoid components and humeral components. Both the subject device and the additional predicate device include preoperative planning of glenoid components and humeral components. The primary differences between subject device and the additional predicate are minor visual and layout differences in the user interface, and segmentation is performed manually for the additional predicate, whereas segmentation is automated (but manually verified) with the subject device.
Performance Data	Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software was considered as a "major" level of concern. Activities included software validation/verification, regression testing, unit testing, code reviews and checks and integration testing.
Conclusion	Based on the intended use, fundamental scientific technology, and the data provided in this Traditional 510(k), Arthrex has determined that the Arthrex Virtual Implant Positioning (VIP) System software (VIP Web Portal and OrthoVis Preoperative Plan) is substantially equivalent to the predicate device.