Arthrex Inc.
Ivette Galmez
Regulatory Affairs Prinicipal Specialist
1370 Creekside Boulevard
Naples, Florida 34108

March 8, 2023

Re: K222007
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, KWS, PHX, LLZ
Dated: February 9, 2023
Received: February 10, 2023

Dear Ivette Galmez:

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: 2023.03.08 12:24:11 -05'00'

For Jiping Chen, MD, Ph.D., M.P.H.
Division 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)*

K222007

Device Name

Arthrex Virtual Implant Positioning (VIP) System - VIP Glenoid Instrumentation

Indications for Use *(Describe)*

The VIP Glenoid Targeter is a 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 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 intended for use with the VIP Glenoid Targeter in total shoulder systems that utilize a central guide pin for preparing the glenoid to receive the glenoid implant. 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 VIP glenoid instrumentation 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.

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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)*

K222007

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 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)

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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)*

K222007

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 glenoid 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) and Univers Revers™ modular glenoid system (MGS) baseplates.

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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510(k) Summary

Date Prepared	March 7, 2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Ivette Galmez Regulatory Affairs Principal Specialist 1-239-643-5553, ext. 71263 ivette.galmez@arthrex.com
Name of Device	Arthrex Virtual Implant Positioning (VIP) System
Common Name	Total shoulder replacement system/instruments, Preoperative planning software/plan, Preoperative Planning Web software
Product Code	QHE, KWS, PHX, LLZ
Classification Name	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class	II
Primary Predicate	K162697: Arthrex Glenoid Intelligent Reusable Instrument System, Arthrex OrthoVis Preoperative Plan, SmartBase for Arthrex Glenoid Iris, Arthrex VIP Web Portal
Secondary Predicate	K212560: Signature™ ONE System
Reference Device	K193523: Arthrex VIP Web Portal
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain clearance for the VIP glenoid reamers as a line extension to the Arthrex VIP System cleared under K162697. This submission includes modifications to the VIP glenoid targeter (formerly glenoid IRI) which were previously documented via letter to file, and VIP software updates.
Device Description	The subject VIP glenoid reamers are made of stainless-steel. The subject device is designed for use with the Univers VaultLock glenoid and Univers Revers MGS baseplates. These glenoid components are within the indications cleared for Arthrex VIP System under K162697 and K193523. The subject VIP glenoid reamers consist of a primary reamer (pilot) and a secondary reamer (glenoid-implant specific: Univers VaultLock [with/without augment] or Univers Revers MGS [with/without augment]). The reaming depth settings for the subject devices is provided with the surgeon approved plan.
Indications for Use	The **VIP Glenoid Targeter** is a 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 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 intended for use with the VIP Glenoid Targeter in total shoulder systems that utilize a central guide pin for preparing the glenoid to receive the glenoid implant. 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 VIP glenoid instrumentation is intended to be used are the same as those described in the labeling for these shoulder systems. The **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 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.

Indications for Use (continue)	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 glenoid 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) and Univers Revers™ modular glenoid system (MGS) baseplates.
Summary of Technological Characteristics	The subject VIP glenoid reamers, except for the secondary reamers for the augmented MGS, are reusable instruments. All VIP glenoid reamers are made of stainless steel. The subject VIP reamers are used in conjunction with the VIP glenoid targeter instrument. The subject VIP reamers are used in place of the standard glenoid reaming instrumentation. The subject reamers are designed with depth control features having similar function to the disposable reaming guide instrumentation in Zimmer-Biomet Signature One system (K212560). The settings for the reaming depth are reviewed during preoperative planning and approved by the surgeon. The reaming depth settings for the subject devices is provided with the surgeon approved plan. The subject VIP glenoid instrumentation has the same fundamental scientific technology (transfer a pre-operative plan to the orthopedic surgical procedure) as the primary predicate (K162697) and secondary predicate (K212560).
Performance Data	Design verification (compression testing and side-by-side testing) and cadaver validation were performed. Compression testing was conducted to assess the function of the depth control features of the VIP glenoid reamers. Side-by-side testing with the standard reaming method was conducted to assess the primary reaming depth control accuracy of the VIP Reaming Instrumentation System. Cadaveric validation was performed to validate the related user needs, intended use, safety and effectiveness of the subject VIP glenoid instrumentation. Software verification and validation testing of the Arthrex VIP Web Portal software and Arthrex OrthoVis Desktop software 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	The subject devices are substantially equivalent to the predicates in which the basic design features, technological characteristics, principles of operation and intended use and indications are similar or the same as the predicates. The verification and validation activities conducted for the subject VIP glenoid reamers demonstrates that it performs as intended for the desired indications. The subject VIP glenoid reamers, when used in conjunction with the Arthrex VIP System is substantially equivalent to the predicate. The addition of the subject VIP glenoid reamer, as well as the modifications to the VIP glenoid targeter and software updates do not raise new questions of safety or effectiveness. The overall planning process, materials, sterilization methods, principles of operation, have not changed from the predicates. Any differences with the predicate are considered minor and do not raise questions regarding safety or effectiveness. Based on the intended use and indications, technological characteristics, principle of operation and the summary of data submitted, Arthrex Inc. has determined that the subject device is substantially equivalent to the currently marketed predicate device.