



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

October 2, 2024

Re: K241097

Trade/Device Name: Arthrex Virtual Implant Positioning (VIP) System Software  
Regulation Number: 21 CFR 888.3660  
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: Class II  
Product Code: QHE  
Dated: August 25, 2024  
Received: August 26, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Joseph P. Russell** Digitally signed by Joseph P.  
Russell -S  
-S Date: 2024.10.02 13:54:33 -04'00'

for: Farzana Sharmin, PhD  
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

## Indications for Use

Submission Number (if known)

K241097

Device Name

Arthrex Virtual Implant Positioning (VIP) System Software

Indications for Use (Describe)

### VIP Web Portal:

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.

### OrthoVis Preoperative Plan:

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.**

## 510(k) Summary

<b>Date Prepared</b>	October 1, 2024
<b>Submitter</b>	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
<b>Contact Person</b>	Troy Brooks, RAC Manager, Regulatory Affairs 1-239-643-5553 Troy.Brooks@Arthrex.com
<b>Name of Device</b>	Arthrex Virtual Implant Positioning (VIP) System software (VIP Web Portal and OrthoVis Preoperative Plan)
<b>Common Name</b>	Preoperative Planning Software
<b>Product Code</b>	QHE
<b>Classification Name</b>	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis
<b>Regulatory Class</b>	II
<b>Primary Predicate</b>	K230904: Arthrex Virtual Implant Positioning (VIP) System software (VIP Web Portal and OrthoVis Preoperative Plan)
<b>Additional Predicate</b>	K232265: Blueprint Patient Specific Instrumentation (Tornier SAS)
<b>Purpose of Submission</b>	This Traditional 510(k) premarket notification is submitted to obtain clearance for modifications made to the existing Arthrex Virtual Implant Positioning (VIP) System software (VIP Web Portal and OrthoVis Preoperative Plan) cleared under K230904.
<b>Device Description</b>	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 shoulder 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.
<b>Indications for Use</b>	<p><b>VIP Web Portal:</b></p> <p>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.</p> <p>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.</p> <p><b>OrthoVis Preoperative Plan:</b></p> <p>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.</p> <p>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.</p>

	<p>The VIP Glenoid Reamer is indicated for use with the Univers VaultLock® glenoid component and the Univers Revers™ modular glenoid system (MGS) baseplates.</p> <p>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.</p>
<b><i>Summary of Technological Characteristics</i></b>	<p>The subject device and predicate device have identical indications for use and intended use. As compared to the predicate device, the subject device includes a Range of Motion feature, Osteophyte Removal feature, a Multiple Plan creation feature, and minor updates to the user interface.</p>
<b><i>Performance Data</i></b>	<p>Software verification and validation testing were conducted and Enhanced Level documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff “Content of Premarket Submissions for Device Software Functions” dated June 14, 2023. Activities included software validation/verification, regression testing, unit testing, code reviews and checks and integration testing.</p>
<b><i>Conclusion</i></b>	<p>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 devices. Any differences between the proposed and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.</p>