September 26, 2023

Arthrex Inc
Tiffany Mentzel
Principal Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K230513
Trade/Device Name: Arthrex Univers Apex OptiFit Humeral Stem
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: August 30, 2023
Received: August 30, 2023

Dear Tiffany Mentzel:

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: 2023.09.26 17:39:19 -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)*
K230513

Device Name
Arthrex Univers Apex OptiFit Humeral Stem

Indications for Use *(Describe)*
The Arthrex Univers Apex OptiFit Humeral Stem is indicated in replacement when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4- part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or re-sectional arthroplasty is not acceptable.

The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.

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

Date Prepared	September 22, 2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Tiffany Mentzel Title: Principal Regulatory Affairs Specialist Phone: 1 (239) 643-5553 x 75833 Email: tiffany.mentzel@arthrex.com
Trade Name	Arthrex Univers Apex OptiFit Humeral Stem
Common Name	Univers Apex OptiFit Humeral Stem
Product Code	KWS, HSD
Classification Name	21 CFR 888.3660: Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented 21 CFR 888.3690: Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Regulatory Class	II
Primary Predicate Device	K131633: Arthrex Univers Apex
Reference Devices	K153115: Arthrex Univers Apex, Size 5 Stem K172371: Arthrex Univers Reverse Coated Baseplate
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Univers Apex OptiFit Humeral Stem.
Device Description	The proposed Univers Apex OptiFit Humeral Stem is the humeral stem component of a shoulder prosthesis system. It consists of a stem, a trunion, an inclination block, pins, and screws. All the components are comprised of titanium with a titanium plasma spray (TPS) coating.
Indications for Use	The Arthrex Univers Apex OptiFit Humeral Stem is indicated in replacement when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4- part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or re-sectional arthroplasty is not acceptable. The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.
Performance Data	Yield strength testing was performed on samples with and without titanium plasma spray coating (TPS). The acceptance criteria were met for all samples, demonstrating substantial equivalence.

	Additional computational electromagnetic simulation testing per FDA guidance, “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” to assess RF heating in bone tissue demonstrated that the Arthrex Shoulder Systems are “MR Conditional.”
Technological Comparison	The proposed device has the same technological characteristics (material, sterilization method and biocompatibility profile). The Arthrex Univers Apex OptiFit Humeral Stem are substantially equivalent to the predicate device in which the design features and intended uses are the same. Any differences between the proposed device and the predicate devices are considered minor and do not result in new or different questions concerning safety or effectiveness.
Conclusion	The Arthrex Univers Apex OptiFit Humeral Stem are substantially equivalent to the predicate devices in which the basic design features and intended use are the same. Any differences between the proposed device and the predicate devices are considered minor and do not result in new or different questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex has determined that the proposed device is substantially equivalent to the currently marketed predicate device.