August 29, 2023

FH Industrie
℅ Christine Scifert
Partner
MRC Global, LLC
9085 E. Mineral Cir., Suite 110
Centennial, Colorado 80112

Re: K232226
Trade/Device Name: ARROW Off-Centred Humeral Insert
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: July 26, 2023
Received: July 27, 2023

Dear Christine Scifert:

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: 2023.08.29 17:30:58 -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)*

K232226

Device Name
ARROW Off-Centred Humeral Insert

Indications for Use *(Describe)*
The ARROW Off-Centred Humeral Insert is designed for the following indications:

REVERSE PROSTHESIS (POROUS GLENOID IMPLANT)
The ARROW Reverse Shoulder Prosthesis is indicated for patients with severe shoulder arthropathy and a grossly deficient rotator cuff or a previously failed shoulder joint replacement with a grossly deficient rotator cuff. A functional deltoid muscle and adequate glenoid bone stock are necessary to use this device. The humeral stem is intended for cemented or cementless application while the porous glenoid baseplate is intended for cementless application with the addition of bone screws for fixation.

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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510(k) Summary
FH Industrie ARROW Off-Centred Humeral Insert
29 August 2023

Company: FH INDUSTRIE
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Official Correspondent: Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

Trade Name: ARROW Off-Centred Humeral Insert

Common Name: Shoulder Prosthesis, Reverse Configuration

Classification: Class II

Regulation Number: 21 CFR 888.3660 (Shoulder joint metal/polymer semi-constrained cemented prosthesis)

Panel: Orthopedic

Product Code: PHX

Device Description:
The ARROW Off-Centered Humeral Insert is used for reverse shoulder prosthesis, with implants of Arrow Reverse Shoulder System (K112193 and K150568), similar to the standard version. This is a modification of the standard ARROW reverse prosthesis (K112193), with the purpose of reducing lateralization of the prosthesis, increase the range of motion, and provide better adaptation for patient anatomy. The ARROW Off-Centered Humeral Insert is made up of four components. All components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI) per ASTM F-136/ISO 5832-3, polyethylene UHMWPE per ASTM F648/ISO 5834-1, and stainless steel 316L per ASTM F138/ISO 5832-1, identical to the previous ARROW Humeral Insert cleared in the 510(k) file ARROW Reverse Shoulder System (K112193). All components are provided sterile via gamma irradiation.

Indications for Use:
The ARROW Off-Centred Humeral Insert is designed for the following indications:

REVERSE PROSTHESIS (POROUS GLENOID IMPLANT)

The ARROW Reverse Shoulder Prosthesis is indicated for patients with severe shoulder arthropathy and a grossly deficient rotator cuff or a previously failed shoulder joint replacement with a grossly deficient rotator cuff. A functional deltoid muscle and adequate glenoid bone stock are necessary to use this device. The humeral stem is intended for cemented or cementless application while the porous glenoid baseplate is intended for cementless application with the addition of bone screws for fixation.

Substantial Equivalence:

The subject ARROW Off-centred humeral insert components are substantially equivalent with respect to indications for use, design, dimension, and materials to the following devices, previously cleared by the FDA:

Primary Predicate:

- FH Industrie: Arrow Reverse Shoulder System – K112193 and K150568

Secondary Predicates:

- Tornier Aequalis ASCEND FLEX Shoulder System– K122698
- FH Industrie: Arrow reverse Porous Glenoid: K171789
- Tornier Aequalis Reversed Shoulder System – K132285

Instrument Biocompatibility Reference Device: ARROW Anatomical Shoulder System – K093599

The Indications for Use, Materials, and Dimensions for primary predicate are identical to those of the subject device with the exception of the offset of the humeral insert. Performance testing and analysis has shown the subject to perform as well as or better than the predicate devices. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Sterilization (ISO 11137), packaging (ISO 11607), and biocompatibility (ISO 10993-1), and bacterial endotoxin (LAL) validations and rationales were conducted and provided to demonstrate substantial equivalence.

Mechanical performance testing and analysis, including connection between stem and humeral insert per ASTM F2009 and Range of Motion, reverse prosthesis per ASTM F1378 has been performed on the subject ARROWoff-centred Humeral Insert. The results have shown them to be substantially equivalent to the predicate devices.

The results of all mechanical tests have shown them to be substantially equivalent to the predicate device.

Conclusion

Based on the test results and the comparison to the predicate device, the subject device is determined to be substantially equivalent to the predicate device.