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

November 30, 2021

Re: K202024
Trade/Device Name: ARROW Short Stem Humeral System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD, KWS
Dated: October 27, 2021
Received: October 28, 2021

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,

For Jiping Chen, Ph.D., M.P.H.
Acting 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202024

Device Name
ARROW Short Stem Humeral System

Indications for Use *(Describe)*
The prostheses from FH Industrie are designed for specific indications such as:
SIMPLE HUMERAL PROSTHESIS
- Humeral head necrosis without injury to the glenoid cavity.
- Extensive humeral head cartilage damage without injury to the glenoid cavity
- Centred osteoarthritis with a glenoid cavity not allowing implantation of a glenoid implant.
- Rheumatoid polyarthritis with thin rotator cuff.
- Off-centred osteoarthritis with irreparable cuff, and with maintained active elevation of at least 120°.

TOTAL ANATOMICAL PROSTHESIS (CEMENTED GLENOID IMPLANT WITH 4 PEGS)
- Centred glenohumeral osteoarthritis with functional rotator cuff
- Rheumatoid polyarthritis with functional rotator cuff
- Post-traumatic sequela, functional rotator cuff with glenoid injury.

TOTAL ANATOMICAL PROSTHESIS (POROUS GLENOID IMPLANT)
- Centred glenohumeral osteoarthritis
- Rheumatoid polyarthritis
- Post-traumatic sequela with glenoid injury
- Revision for glenoid loosening
- Glenoid bone loss, where bone graft is needed

A functional rotator cuff is necessary to use this device

REVERSE PROSTHESIS (METAL-BACK OR 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.

For all types of prosthesis, the glenoid baseplate (metal-back or porous) is intended for cementless use with the addition of bone screws for fixation, the humeral short stem (metaphyseal stem and diaphyseal stem) is intended for cementless use. At least 2/3 of the metaphyseal component must be implanted in the proximal humeral bone to allow for adequate humeral component 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 Short Stem Humeral System
29 November 2021

Company: FH INDUSTRIE
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Official Correspondent: Christine Scifert – MRC Global, LLC
(901) 831-8053

Trade Name: ARROW Short Stem Humeral System

Common Name: Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented
Shoulder Prosthesis, Reverse Configuration
Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented

Classification: Class II

Regulation Number: 21 CFR 888.3690 (Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis)
21 CFR 888.3660 (Shoulder Prosthesis, Reverse Configuration)

Panel: Orthopedic

Product Code: PHX, HSD,KWS

Device Description:
The ARROW Humeral Short Stem Humeral System is an extension of humeral stem range of the Arrow prosthesis. The short stem is composed of a metaphyseal part and a cylindrical diaphyseal part. Both components are offered in various sizes to accommodate patient anatomy. This modular stem helps for better adaptation to each patient's anatomy. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI) per ASTM F-136/ISO 5832-3. The metaphysis has fins to provide rotational stability; it has a pure titanium plasma spray coating per ASTM 1580.

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At least 2/3 of the metaphyseal component must be implanted in the proximal humeral bone to allow for adequate humeral component fixation.

Substantial Equivalence:

The subject ARROW Humeral Short Stem Humeral System 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 Humeral Stem - K112193

Additional Predicates:

- FH Industrie, Arrow Humeral Stem - K093599, K150569
- Exactech, Equinoxe Preserve Stem – K162726
- DJO, Altivate Preserve – K190290
- Biomet, Comprehensive Micro – K060692, K080642
- Depuy Delta III – K021478

Reference devices /Biocompatiblity Predicates:

Fournitures Hospitalieres Industrie: ARROW Glenoid base porous (K162068, K171789)

The Indications for Use, Materials, and Geometry for predicate devices are all similar to those of the subject device. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Sterilization (ISO 11137) and packaging (ISO 11607) validations , and biocompatibility (ISO 10993-1) assessment and testing were conducted and provided to demonstrate substantial equivalence. Bacterial endotoxin levels were evaluated using LAL pyrogen testing.

Mechanical testing, including the following was performed on the subject devices:

- connection between stem and head per ASTM F 2009
- connection between stem and humeral insert per ASTM F 2009
- static test on the connection between metaphysis and diaphysis
- fatigue test on short stem - below the connection
- fatigue test on short stem - above the connection
- range of motion for anatomical prosthesis per ASTM F1378
- range of motion for reverse prosthesis per ASTM F1378
- fatigue testing per ASTM F2580
- corrosion testing
- connection dynamic torsional resistance
- connection static torsion

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 devices, the subject device is determined to be substantially equivalent to the predicate devices.