October 29, 2025

FH Industrie
% Christine Scifert
Partner
MRC Global
9085 East Mineral Circlie
Suite 110
Centennial, Colorado 80112

Re: K253345
Trade/Device Name: JARVIS Diaphyseal Stem Standard
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: September 29, 2025
Received: September 30, 2025

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 (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2025.10.29 16:33:58 -04'00'

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253345

Please provide the device trade name(s).

JARVIS Diaphyseal Stem Standard

Please provide your Indications for Use below.

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 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 and JARVIS 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 (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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
JARVIS Diaphyseal Stem Standard
27 October 2025

Company:	FH INDUSTRIE ZI DE KERNEVEZ-6 RUE NOBEL QUIMPER Finistere, FRANCE 29000
Company Contact:	Naoual RAHIMI- FH Industrie Regulatory Affairs Manager n.rahimi@fhortho.com +33 (0)2 98 55 68 95
Official Correspondent:	Christine Scifert – MRC Global, LLC Christine.scifert@askmrcglobal.com 901-831-8053
Trade Name:	JARVIS Diaphyseal Stem Standard
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:	HSD, PHX, KWS
Primary Predicate:	FH Industrie: ARROW Short Stem – K202024
Additional Predicates:	FH Industrie – ARROW Humeral Stem – K093591, K112193, K150568

Device Description:
The JARVIS Diaphyseal Stem Standard is an extension of humeral stem range of the Arrow prosthesis. The JARVIS Diaphyseal Stem Standard is intended to be used with the Metaphyseal component of the modular ARROW Short Stem device (K202024). The JARVIS Diaphyseal Stem Standard is offered in various sizes to accommodate patient anatomy. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI) per ASTM F-136/ISO 5832-3.

Indications for Use:

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 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

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For all types of prosthesis, the glenoid baseplate (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.

Substantial Equivalence:

The Indications for Use, Materials, and overall technology for predicate device are identical to that of the subject device. The overall geometry falls within the range of the predicate devices. The previously cleared ARROW Humeral Stem size range encompasses all diameters offered by the subject device and assembled length of the subject device in construct with the metaphyseal components is encompassed by the fully assembled length of the ARROW humeral stem while the connection between components is identical to that of the ARROW Short Stem. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Engineering analysis has determined that no new worst case has been introduced by the subject devices. The connection of the subject devices is identical to that of the predicate ARROW Short Stem

and the modification of the diaphyseal component is not expected to impact performance. Therefore, previously performed testing is applicable to the subject device and no additional performance testing is required.

Conclusion

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