August 28, 2025

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

Re: K252411
Trade/Device Name: JARVIS Glenoid Reverse Shoulder Prosthesis
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 31, 2025
Received: August 1, 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2025.08.28 13:19:13 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252411

Device Name

JARVIS Glenoid Reverse Shoulder Prosthesis

Indications for Use *(Describe)*

REVERSE PROSTHESIS
The Jarvis Glenoid 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.
The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary. The glenoid baseplate is intended for cementless application with the addition of 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.

510(k) Summary
JARVIS Glenoid Reverse Shoulder Prosthesis
27 August 2025

Company: FH INDUSTRIE
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QUIMPER Finistere, FRANCE 29000

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

Trade Name: JARVIS Glenoid Reverse Shoulder Prosthesis

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

Primary Predicate: FH Industrie: JARVIS Glenoid Reverse Shoulder Prosthesis – K242253

Device Description:
The JARVIS Glenoid Reverse Shoulder Prosthesis is used for reverse shoulder prosthesis, intendedfor primary, fracture or revision shoulder replacement. The JARVIS Glenoid Reverse Shoulder Prosthesis is made up of three components – glenophere, baseplate, and fixation component (screw or post) . All components are offered in varying sizes to accommodate patient anatomy. The baseplate and screw components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI) per ASTM F-136/ISO 5832-3, while the glenophere is manufactured from wrought cobalt chromium molybdenum alloy per ASTM F1537/ISO 5832-12. All components are provided sterile via gamma irradiation.

The subject submission seeks to gain clearance for design modifications to the existing device components.

Indications for Use:

REVERSE PROSTHESIS

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Substantial Equivalence:

The subject device indications for Use, Materials, and overall Dimensions for the predicate devices are identical to those of the subject device. The overall technology of the subject devices is the same as the predicate JARVIS system. The subject modifications to thread all holes of the baseplate and change the locking screw threading do not impact the technology of the device, only enhance the design. Thus, it can be concluded that the subject does not raise different questions about safety and effectiveness.

Performance Testing:

Engineering analysis was conducted on the modified locking screws and concluded that the compressive force of the subject screws is equivalent to that of the predicate and therefore locking capabilities are equivalent. Therefore, all previous performance testing and validations are still applicable and no additional testing is necessary.

Conclusion

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