November 25, 2024

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

Re: K242253
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, KWS, KWT
Dated: October 4, 2024
Received: October 4, 2024

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: 2024.11.25 18:42:03 -05'00'

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

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)*

K242253

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
25 November 2024

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 56 10 20 46
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 Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented
Classification:	Class II
Regulation Number:	21 CFR 888.3660 (Shoulder joint metal/polymer semi-constrained cemented prosthesis) 21 CFR 888.3650 (Shoulder joint metal/polymer non-constrained cemented prosthesis)
Panel:	Orthopedic
Product Code:	PHX, KWS, KWT
Primary Predicate:	FH Industrie: Arrow Reverse Shoulder System – K171789
Additional Predicates:	FH Industrie: Arrow Reverse Shoulder System – K112193 Integra LifeSciences Corporation; TITAN Reverse Shoulder System – K190588 Zimmer Comprehensive Reverse Shoulder System – K193373 FX Shoulder Humelock Reversed Shoulder – K162455 Tornier Aequalis PerFORM Reversed, Aequalis PerFORM+ Reversed Glenoid – K161742

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.

Indications for Use:

REVERSE PROSTHESIS

The 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. 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.

Substantial Equivalence:

The subject device is an expansion of FH Ortho's shoulder portfolio, designed to provide surgeons with options when a reverse shoulder prosthesis is needed. Indications for Use, Materials, and Dimensions for the predicate devices are similar to those of the subject device. Performance testing has shown that the subject meets or exceeds acceptance criteria. Thus, it can be concluded that the subject does not raise different 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 including Axial disassembly of baseplate/glenophere taper connection per ASTM F2009; Shear disassembly of baseplate/glenosphere taper connection per ASTM F1829; Torsion, Driving Torque, Self tapping performance, and Axial Pullout per ASTM F543; baseplate with compensation loosening test per ASTM F2028; Range of Motion, reverse prosthesis per ASTM F1378; fixation on baseplate testing; post fatigue shear disassembly, axial disassembly per ASTM F2028/ASTM F2009; Post Fatigue Torsion per ISO 7206-13; and Fretting and Corrosion per ASTM F2009/ ASTM F1875 has been performed on the subject JARVIS Reverse Shoulder Prosthesis. The results have shown them to meet or exceed acceptance criteria.

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.