



June 5, 2023

FX Shoulder USA, Inc  
Cory Trier  
Quality Assurance Associate  
13465 Midway Road, Suite 101  
Dallas, Texas 75244

Re: K223801

Trade/Device Name: FX V135™ 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, KWT, HSD  
Dated: May 5, 2023  
Received: May 5, 2023

Dear Cory Trier:

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](mailto: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: 2023.06.05  
16:29:19 -04'00'

For: Farzana Sharmin, Ph.D.  
Acting 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

510(k) Number (if known)  
K223801

Device Name  
FX V135™ Shoulder Prosthesis

### Indications for Use (Describe)

In an anatomic shoulder configuration, the FX V135™ Shoulder System is indicated for use in total and hemi-shoulder replacement to treat:

- a severely painful and/or disabled joint resulting from osteoarthritis or rheumatoid arthritis;
- other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a previously implanted primary component, a humeral plate or a humeral nail).

In a reverse shoulder configuration, the FX V135™ Shoulder is indicated for primary or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with massive and non-repairable rotator cuff tear.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The humeral stem of the FX V135™ Cementless Shoulder is intended for cementless use only, with optional cortical bone screws for the longer stems. The glenoid components of the FX V135™ Shoulder System are intended for cemented use only. The glenoid baseplate component is intended for cementless use 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.

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**7. 510(k) Summary**

**Applicant/Sponsor:** FX Shoulder USA, Inc.  
13465 Midway Road, Suite 101  
Dallas, Texas 75244  
Establishment Registration No: 3014128390

**Manufacturer:** FX Solutions  
1663 Rue de Majornas  
Viriat, France 01440  
Establishment Registration No: 3009532798

**Contact Person:** Cory Trier  
Quality Assurance Associate  
260.610.1028

**Date:** June 2, 2023

**Proprietary Name:** FX V135™ Shoulder Prosthesis

**Common Name:** Anatomic and Reverse Shoulder Prosthesis

**Product Code(s):** PHX, KWT, HSD

**Classification Name:** 21 CFR 888.3650: shoulder joint metal/polymer non-constrained cemented prosthesis – Class II  
21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis – Class II  
21 CFR 888.3690 shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis – Class II

**Substantially Equivalent Devices:** Primary Predicate:  
FX V135™ Shoulder Prosthesis (K213117)  
Reference Device:  
Humelock Reversed® Shoulder (K162455)  
Encore Humeral Shoulder Stem (K141990)

## **Device Description**

The FX V135™ Shoulder Prosthesis is a shoulder replacement system that may be used as a total or hemi shoulder replacement in either an anatomic or a reversed shoulder construct. The new components of the system included in this submission are the FX V135™ Additional Humeral Stems that are added to the system as a line extension of the cementless humeral stems.

The FX V135™ Shoulder Prosthesis is manufactured from Ti-6Al-4V ELI alloy conforming to ISO 5832-3 and are available in diameters of 8-16mm in the diaphysis dependent upon the epiphyseal size 32, 36, and 40mm. The longer stems added to the system are available in lengths 120mm, 180mm and 200mm. The proximal portion of the humeral stem has a plasma sprayed commercially pure Titanium (CP-Ti) and Hydroxyapatite (HA) coating. The distal end of the humeral stem is cylindrical and bead blasted with unthreaded screw holes oriented in the medial / lateral direction for optional fixation using cortical bone screws.

The FX V135™ Shoulder Prosthesis incorporates a female taper for attachment of compatible components.

The FX V135™ Shoulder Prosthesis can be used with previously cleared components including a taper adapter, a centered or offset humeral head and a 2 peg or 3 or 4 peg cemented glenoid for use in an anatomic shoulder configuration.

For reverse configuration, the FX V135™ Shoulder Prosthesis can be used with a humeral cup and optional spacer, a centered or eccentric glenosphere with or without a central screw, a glenoid baseplate (with or without a central screw), optional post extensions and standard (compression) and locking bone screws around the periphery of the baseplate. The previously cleared Humeral Cups mate with the FX V135™ Additional Humeral Stems to complete the reverse configuration.

## **Intended Use / Indications**

In an anatomic shoulder configuration, the FX V135™ Shoulder System is indicated for use in total and hemi-shoulder replacement to treat:

- a severely painful and/or disabled joint resulting from osteoarthritis or rheumatoid arthritis;
- other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a previously implanted primary component, a humeral plate or a humeral nail).

In a reverse shoulder configuration, the FX V135™ Shoulder System is indicated for primary or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with massive and non-repairable rotator cuff tear.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The humeral stem of the FX V135™ Cementless Shoulder is intended for cementless use only, with optional cortical bone screws for the longer stems. The glenoid components of the FX V135™ Shoulder System are intended for cemented use only. The glenoid baseplate component is intended for cementless use with the addition of screws for fixation.

### **Summary of Technologies / Substantial Equivalence**

The new FX V135™ Shoulder Prosthesis is substantially equivalent to the primary predicate in that they are identical to the primary predicate on indications, material, packaging, single use, sterilization, shelf life, pyrogen testing, biocompatibility, compatible components and identical in design except for length. The subject devices are longer than the primary predicate with 120mm, 180mm, 200mm lengths. The new FX V135™ Shoulder Prosthesis is similar in design to the Reference Device K162455 with distal holes for cortical bone screws and similar in design to the Reference Device K141990 with proximal suture holes and within the size range. The subject device, FX V135™ Shoulder Prosthesis, is added to the cleared FX V135™ Shoulder System as a line extension, does not raise different questions of safety and effectiveness, and is substantially equivalent to the predicates.

### **Non-Clinical Testing**

Range of motion analysis demonstrated comparability to the predicate device. Construct fatigue testing was completed with test constructs completing all cycles with no failures and taper connections remaining firmly fixed. The results of these tests indicate that the performance of the FX V135™ Shoulder Prosthesis is adequate for its intended use and substantially equivalent to the predicate device.

### **Clinical Testing**

Clinical testing is not necessary to determine substantial equivalence of the FX V135™ Shoulder Prosthesis to the predicate device.

### **Conclusions**

Based upon the risk assessment and pre-clinical testing to characterize device performance, substantial equivalence to the predicate device is demonstrated. The FX V135™ Shoulder Prosthesis is substantially equivalent based upon indications, design, material, packaging, single use, sterilization, shelf life. The FX V135™ Shoulder Prosthesis is expected to be as safe, as effective, and perform as well as the legally marketed predicate device.