FX Shoulder USA, Inc.
Kathy Trier
VP Regulatory, Quality, Clinical, Compliance
13465 Midway Road, Suite 101
Dallas, Texas 75244

June 7, 2022

Re: K213117
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: April 29, 2022
Received: May 2, 2022

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

Sincerely,

For Jiping Chen, M.D., 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K213117

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. 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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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:	Kathy Trier, Ph.D. VP Regulatory, Clinical, Quality, Compliance
Date:	June 7, 2022
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 21 CFR 888.3660 shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3690 shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Substantially Equivalent Devices:	Primary Predicate: Humeris Shoulder System (K163669) Reference Device: PERFORM Humeral System – Stem (K201315)

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 this system include the FX V135 cementless humeral stems, the new

Humeral Cup 135/145º and a new humeral spacer on the reverse configuration, and on the anatomic configuration, the new humeral stem and new humeral heads.

The Humeral Stem of the FX V135 Shoulder Prosthesis is manufactured from Ti-6Al-4V ELI alloy conforming to ISO 5832-3 and is available in diameters of 10-20mm in the diaphysis dependent upon the epiphyseal size 32, 36, or 40mm. All have a length of 70mm. The distal end of the humeral stem is quadrangular and bead blasted. The proximal portion of the humeral stem has a plasma sprayed commercially pure Titanium (CP-Ti) and Hydroxyapatite (HA) coating.

The FX V135 Humeral Stems incorporate a female taper for attachment of compatible components.

The new FX V135 Humeral Head is available in two versions and are manufactured from CoCrMo alloy conforming to ISO 5832-12. The new FX V135 Humeral Cup 135/145° is available in three sizes, Ø32, Ø36 and Ø40mm. Each size is available in two versions, standard and stability. Each version is available in three heights: +3mm, +6mm, +9mm; and is compatible with all sizes of FX V135 Humeral Stems. The FX V135 Humeral Cup 135/145º is pre-assembled, one-piece component manufactured from ultra high molecular weight polyethylene (UHMWPE) conforming to ISO5834-2 and Ti-6Al-4V ELI alloy conforming to ISO 5832-3. The new Humeral Cup 135/145° may be used with the new Humeral Spacer +9mm to increase the cup offset.

The FX V135 Humeral Stems 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 anatomical shoulder configuration.

For reverse configuration, the FX V135 Humeral Stem 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) or locking bone screws around the periphery of the baseplate. The previously cleared Humeral Cups or the subject Humeral Cup 135/145º mate with the FX V135 Humeral Stem to complete the reverse configuration.

Indications for Use:
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. 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 FX V135 Shoulder Prosthesis is substantially equivalent to the predicate device in regards to its intended use and indications, materials, and similar design and sizes, The subject device is similar in design and sizes to the reference device. Differences between the subject device system and the predicate device systems do not raise different questions of safety and effectiveness.

Non-Clinical Testing

Range of motion analysis demonstrated substantial equivalence to 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 was not necessary to determine substantial equivalence of the FX V135 to the predicate device.

Summary

Based upon the assessment of substantial equivalence regarding the indications, material, packaging, single use, sterilization, shelf life, pyrogen testing, biocompatibility, and the nonclinical testing and assessment of the risk associated with the device design compared to the primary predicate submitted here, the FX V135 Shoulder Prosthesis is expected to be as safe, as effective, and perform as well as the legally marketed predicate device.