May 1, 2026

FX Shoulder Solutions, Inc.
Cory Trier
RA II / Compliance Project Manager
15920 Addison Rd. Suite 200
Addison, Texas 75001

Re: K254154
Trade/Device Name: FX V135 EASYTECH® Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC, PHX, KWT, HSD
Dated: April 2, 2026
Received: April 3, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K254154

Device Name
FX V135 EASYTECH® Shoulder System

Indications for Use *(Describe)*
The FX V135 EASYTECH® Shoulder System is intended for use in shoulder replacement to treat a severely painful and/or disabled joint.

In an anatomic shoulder configuration, the humeral stemless anchor base of FX V135 EASYTECH® Shoulder System is indicated for cementless use only in primary total shoulder replacement to treat:
- A severely painful and/or disabled joint resulting from osteoarthritis or rheumatoid arthritis;

In an anatomic shoulder configuration requiring a total, revision or hemi-shoulder, the humeral stemless anchor base with the addition of the Short humeral stem is indicated for cementless use only to treat:
- 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).

The glenoid components of the FX V135 EASYTECH® Shoulder System in the anatomic construct are intended for cemented use only.

The patient's joint must be anatomically and structurally suited to receive the selected implants.

In a reverse shoulder configuration, the FX V135 EASYTECH® 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 reverse FX V135 EASYTECH® Shoulder System requires the humeral stemless anchor base with the addition of the cementless humeral stem.

In a reverse shoulder configuration, the glenoid components of the FX V135 EASYTECH® Shoulder System are intended for cemented use only. The glenoid baseplate component is intended for cementless use with the addition of screws for fixation.

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.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) Summary**

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|---|---|
| **Applicant/Sponsor**: | FX Shoulder Solutions, Inc.<br>15920 Addison Rd, Suite 200<br>Addison, Texas 75001<br>Establishment Registration No: 3014128390 |
| **Manufacturer:** | FX Shoulder Solutions<br>1663 Rue de Majornas<br>Viriat, France 01440<br>Establishment Registration No: 3009532798 |
| **Contact Person**: | Cory Trier<br>Regulatory Affairs II / Compliance Project Manager |
| **Date**: | December 21, 2025 |
| **Proprietary Name**: | FX V135 EASYTECH® Shoulder System |
| **Common Name**: | Anatomic and Reverse Shoulder Prosthesis |
| **Product Code(s)**: | PKC, PHX, KWT, HSD |
| **Classification Name**: | 21 CFR 888.3650: shoulder joint metal/polymer non-constrained cemented prosthesis – Class II<br>21 CFR 888.3660: shoulder joint metal/polymer semi-constrained cemented prosthesis – Class II<br>21 CFR 888.3690: shoulder joint glenoid (hemi shoulder) metallic uncemented prosthesis – Class II |
| **Substantially Equivalent Devices:** | Primary Predicate:<br>FX V135® Shoulder Prosthesis (K213117)<br><br>Reference Predicate Devices:<br>Easytech® Anatomical Shoulder System (K201391)<br>LIMA Finned Short Stem (K191963) |

**Device Description**

FX V135 EASYTECH® Shoulder System is a shoulder replacement system that may be used as a total shoulder replacement in either an anatomic or a reversed shoulder construct. The basis for this submission is the pre-market notification of new humeral components added to the previously cleared FX V135® Shoulder System (K213117). The new components of this system include the FX V135 EASYTECH® humeral stemless anchor base, short humeral stem, and new humeral cups. Compatible components to complete the system have been cleared previously in K111097, K123814, K163669, K191146, K191698, and K213117.

FX V135 EASYTECH® Shoulder System is indicated for uncemented use. For anatomical configuration, the FX V135 EASYTECH® anchor base can be used as a stemless construct or can be mated to the Short humeral stem as a stemmed construct. For reverse configuration, the FX V135 EASYTECH® anchor base requires the addition of the Short humeral stem.

The FX V135 EASYTECH® anchor base, anchor base / stem connection screw, and short humeral stem are manufactured from Ti6Al4V ELI alloy conforming to ISO 5832-3. The FX V135 EASYTECH® humeral cups are pre-assembled, one-piece components manufactured from ultra-high molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2 and Ti6Al4V ELI alloy conforming to ISO 5832-3.

For the anatomic construct, this implant provides the ability to change a stemless implant to a short, stemmed implant by adding a short humeral stem to the main post intraoperatively. In this way the surgeon has flexibility to continue with the same shoulder component, the anchor base, versus requiring a change to a different shoulder system intraoperatively.

For the anatomic construct, based upon intraoperative bone quality and soft tissue assessment, a humeral stemless anchor base can be combined to a short humeral stem to accommodate for inadequate bone and soft tissue quality. The surgeon may make this determination during preparation of the humeral bone.

**Intended Use / Indications**

**The FX V135 EASYTECH® Shoulder System is intended for use in shoulder replacement to treat a severely painful and/or disabled joint.**

**In an anatomic shoulder configuration**, the humeral stemless anchor base of FX V135 EASYTECH® Shoulder System is indicated for cementless use only in primary total shoulder replacement to treat:

- A severely painful and/or disabled joint resulting from osteoarthritis or rheumatoid arthritis;

**In an anatomic shoulder configuration requiring a total, revision or hemi-shoulder,** the humeral stemless anchor base with the addition of the Short humeral stem is indicated for cementless use only to treat:

- 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).

The glenoid components of the FX V135 EASYTECH® Shoulder System in the anatomic construct are intended for cemented use only.

The patient's joint must be anatomically and structurally suited to receive the selected implants.

**In a reverse shoulder configuration**, the FX V135 EASYTECH® 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 reverse FX V135 EASYTECH® Shoulder System requires the humeral stemless anchor base with the addition of the cementless humeral stem.

In a reverse shoulder configuration, the glenoid components of the FX V135 EASYTECH® Shoulder System are intended for cemented use only. The glenoid baseplate component is intended for cementless use with the addition of screws for fixation.

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.

**Summary of Technologies / Substantial Equivalence**
The FX V135 EASYTECH® Shoulder System is substantially equivalent to the primary predicate in that it has the same indications, is comprised of the same materials, its design is similar in size and incorporates the same design features. Both are provided sterile for single use using gamma irradiation. The subject device and primary predicate conform to recognized performance standards for total shoulder devices. The subject device shares similar characteristics with the stemless reference device and the modular stem reference device. Evaluation of the design differences do not raise new questions of safety or effectiveness. The coating of the subject device is identical to the coating of the reference device.

**Non-Clinical Testing**
Range of motion analysis demonstrated comparability to predicate devices. 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 EASYTECH® Shoulder System is adequate for its intended use and substantially equivalent to the predicate devices.

**Clinical Testing**
Clinical testing was not necessary to determine substantial equivalence of the FX V135 EASYTECH® Shoulder System to the predicate devices.

**Conclusions**
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 design modification of the primary predicate submitted here, the FX V135 EASYTECH® Shoulder System is expected to be as safe, as effective, as the legally marketed device predicate.