FX Shoulder USA, Inc.
Cory Trier
RA/Compliance Associate
15920 Addison Road, Suite 200
Addison, Texas 75001

May 15, 2024

Re: K240278
Trade/Device Name: Full Wedge Lateralized and Augmented Baseplates
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD
Dated: April 9, 2024
Received: April 9, 2024

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 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.

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: 2024.05.15 10:44:13 -04'00'

Farzana Sharmin, Ph.D.
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)*

K240278

Device Name

Full Wedge Lateralized and Augmented Baseplates

Indications for Use *(Describe)*

When used in the Humelock II Reversible Shoulder System:
The Humelock II Reversible Shoulder is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a 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 stems are intended for cemented or cementless use. The metaglene baseplate is intended for cementless use with the addition of screws for fixation.

When used in the Humelock Reversed Shoulder System:
The Humelock Reversed Shoulder is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a massive and non-repairable cuff tear.

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

During primary or revision surgery, if the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or the glenoid bone fractures during the procedure, a taper adapter can be used to convert the Humelock Reversed Shoulder to an anatomic hemi-shoulder prosthesis.

The humeral stem of the Humelock Reversed Cemented Shoulder Prosthesis is intended for cemented use only. The humeral stem of the Humelock Reversed Cementless Shoulder Prosthesis is lockable with two cortical bone screws and is intended for cementless or cemented stems.

The glenoid baseplate and post extension are intended for cementless use with the addition of screws for fixation.

When used in the Humeris Shoulder System and Humeris 135 Shoulder System:
In an anatomic shoulder configuration, the Humeris 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 Humeris Shoulder is indicated for primary or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a 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 Humeris Cementless Shoulder is intended for cementless use only. The humeral stem of the Humeris Cemented Shoulder is intended for cemented use only. The glenoid baseplate component is intended for cementless use with addition of screws for fixation.

When used in the FX V135 Shoulder Prosthesis:
In an anatomic shoulder configuration, the FX V135 Shoulder Prosthesis 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 Prosthesis is indicated for primary or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a 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.

510(k) Summary

Applicant/Sponsor:	FX Shoulder USA, Inc. 15920 Addison Road Suite 200 Addison, Texas 75001 Establishment Registration No: 3014128390
Manufacturer:	FX Solutions 1663 Rue de Majornas Viriat, France 01440 Establishment Registration No: 3009532798
Contact Person:	Cory Trier Regulatory/Compliance Associate
Date:	January 31, 2024
Proprietary Name:	**Full Wedge Lateralized and Augmented Baseplates**
Common Name:	Reverse Shoulder Prosthesis
Product Code(s):	PHX, HSD
Classification Name:	21 CFR 888.3660: shoulder joint metal/polymer semi-constrained cemented prosthesis – Class II 21 CFR 888.3680: shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis – Class II
Substantially Equivalent Devices:	Primary Predicate: Lateralized and Augmented Baseplates (K210790)

Device Description

The Full Wedge Lateralized and Augmented Baseplates are new components added to the reverse shoulder replacement systems including the Humelock II Reversible Shoulder System, the Reversed (K162455), the Humeris Shoulder (K163669, K222936) and the FX V135 Shoulder Prosthesis (K213117, K223801). The Lateralized baseplate with full wedge augmentation is a modification of the primary predicate half wedge lateralized and augmented baseplates (K210790) and may be used with an asymmetric bone defect when there is no possibility to correct this defect without graft or excessive reaming.

Compatible components for use with the Full Wedge Lateralized and Augmented Baseplates are the same as the compatible components for use in the previously cleared reverse shoulder replacement systems.

Intended Use / Indications

When used in the Humelock II Reversible Shoulder System:
The Humelock II Reversible Shoulder is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a 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 stems are intended for cemented or cementless use. The metaglene baseplate is intended for cementless use with the addition of screws for fixation.

When used in the Humelock Reversed Shoulder System:
The Humelock Reversed Shoulder is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a massive and non-repairable cuff tear.

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

During primary or revision surgery, if the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or the glenoid bone fractures during the procedure, a taper adapter can be used to convert the Humelock Reversed Shoulder to an anatomic hemi-shoulder prosthesis.

The humeral stem of the Humelock Reversed Cemented Shoulder Prosthesis is intended for cemented use only. The humeral stem of the Humelock Reversed

Cementless Shoulder Prosthesis is lockable with two cortical bone screws and is intended for cementless or cemented stems.

The glenoid baseplate and post extension are intended for cementless use with the addition of screws for fixation.

When used in the Humeris Shoulder System and Humeris 135 Shoulder System:
In an anatomic shoulder configuration, the Humeris 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 Humeris Shoulder is indicated for primary or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a 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 Humeris Cementless Shoulder is intended for cementless use only. The humeral stem of the Humeris Cemented Shoulder is intended for cemented use only. The glenoid baseplate component is intended for cementless use with addition of screws for fixation.

When used in the FX V135 Shoulder Prosthesis:
In an anatomic shoulder configuration, the FX V135 Shoulder Prosthesis 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 Prosthesis is indicated for primary or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a 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 components, Full Wedge Lateralized and Augmented Baseplates, are identical to the primary predicate, half wedge lateralized augmented baseplates, on indications, material, manufacturing, packaging, single use, sterilization, shelf life, biocompatibility, compatible components. The subject device is a design modification of the primary predicate that do not raise different questions of safety and effectiveness and is substantially equivalent to the primary predicate.

Non-Clinical Testing

Bench testing for glenoid loosening (ASTM F2028-17) was performed and found to be substantially equivalent to the primary predicate. Range of motion analysis has been completed based upon the same parameters and assumptions as the ROM analysis previously submitted for the primary predicate and demonstrates substantial equivalence as well as exceeding ASTM F-1378-18.

Clinical Testing

Clinical testing was not necessary to determine substantial equivalence of the Full Wedge Lateralized and Augmented Baseplates 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 design modification of the primary predicate submitted here, the Full Wedge Lateralized and Augmented Baseplates are expected to be as safe, as effective, and perform as well as the legally marketed device predicate.