FX Shoulder USA, Inc. August 25, 2021
Kathy Trier
VP Regulatory, Quality, Clinical, Compliance
13465 Midway Road, Suite 101
Dallas, Texas 75244

Re: K210790
Trade/Device Name: 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: August 4, 2021
Received: August 5, 2021

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 Michael Owens
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210790

Device Name

Lateralized and Augmented Baseplates

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 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.

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 use only. An optional anti-rotation spoiler can be used with either the cementless or the 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:
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 components of the Humeris 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)*

[X] 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 574.551.1368
Date:	August 17, 2021
Proprietary Name:	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 888.3690 shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis – Class II
Substantially Equivalent Devices:	Primary Predicates: Humelock II Reversible Shoulder System (K150488) Baseplate with Screw (K192799) Reference Device: Aequalis PerFORM Reversed, PerFORM+ Reversed Glenoid (K16742, K183696)

Device Description

The Lateralized and Augmented Baseplates are new components for the Humelock II Reversible Shoulder System. They are also components added to the Humelock

Reversed (K162455) and Humeris Shoulder (K163669), when used for a reverse construct. The Lateralized Baseplate can be used to increase the offset and as needed the Lateralized baseplate with augmentation has an added wedge 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 Lateralized and Augmented Baseplates are the same as those previously cleared compatible components for use as a component in the primary predicate devices, Humelock II Reversible K150488 and Baseplate with Screw K192799, and in the K162455 Humelock Reversed Shoulder System and K163669 Humeris Shoulder, when used for a reverse shoulder construct.

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 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.

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 use only. An optional anti-rotation spoiler can be used with either the cementless or the 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:
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;
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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 components of the Humeris 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, Lateralized and Augmented Baseplates, are identical to the primary predicates on indications, material, manufacturing, packaging, single use, sterilization, shelf life, biocompatibility, compatible components. The subject device is a design modification of the primary predicates. The lateralization and augmentation of the subject devices are similar to the reference device. The offset of lateralization is the same as the reference device and the augmentation of the subject device is within the degree of version correction with augmentation of the reference device. The central screw for that variant of the Baseplate options and the peripheral screws of the subject device are within the range of screws available in the reference device system. Any differences between the subject device and the primary predicate device and reference device do not raise new questions of safety and effectiveness; the FX Shoulder Lateralized and Augmented Baseplates are substantially equivalent to the primary predicate and reference device.

Non-Clinical Testing

Previous bench testing has been submitted in the cleared 510(k) submissions for K150488 and K192799. Range of Motion analysis has been completed based upon the same parameters and assumptions as the ROM analysis previously submitted for the primary predicates and demonstrates substantial equivalence as well as exceeding

ASTM F-1378-18. Glenoid loosening per ASTM F2028 met acceptance criteria and all samples ran to 100,000 cycles with no loosening of glenosphere or baseplate.

Clinical Testing

Clinical testing was not necessary to determine substantial equivalence of the Lateralized and Augmented Baseplates to the predicate devices.

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 predicates submitted here, the Lateralized and Augmented Baseplates are expected to be as safe, as effective, and perform as well as the legally marketed device predicates.