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

November 23, 2022

Re: K222936
Trade/Device Name: Anatomic & Reverse 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

Dear Cory Trier:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 7, 2022. Specifically, FDA is updating this SE Letter as an administrative correction. The original SE letter was not signed.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Victoria Lilling, M.D., OHT6: Office of Orthopedic Devices, (240) 402-4017, Victoria.Lilling@FDA.HHS.gov.

Sincerely,

Victoria A. Lilling -S
Digitally signed by Victoria A. Lilling -S
Date: 2022.11.23 17:57:03 -05'00'

Victoria Lilling, M.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

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

November 7, 2022

Re: K222936
Trade/Device Name: Humeris® 135 Shoulder System
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: September 23, 2022
Received: September 26, 2022

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

Sincerely,

Victoria Lilling, M.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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K222936

Device Name
Humeris® 135 Shoulder System

Indications for Use *(Describe)*

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 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)*

☒ 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.

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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:	Cory Trier Quality Assurance Associate
Date:	September 23, 2022
Proprietary Name:	Humeris® 135 Shoulder System
Common Name:	Reverse Shoulder Prosthesis
Product Code(s):	PHX, KWT, HSD
Classification Name:	21 CFR 888.3660: shoulder joint metal/polymer semi-constrained cemented prosthesis – Class II 21 CFR 888.3650: Shoulder joint metal/polymer semi-constrained cemented prosthesis – Class II 21 CFR 888.3690 shoulder joint glenoid (hemi-shoulder) metallic uncemented prosthesis – Class II
Substantially Equivalent Devices:	Primary Predicate: Humeris® Shoulder System (K163669)

Device Description

The Humeris® 135 Shoulder System adds new components to the previously cleared Humeris Shoulder System (K163669). The additional new components are humeral

cups eccentric symmetric and a Humeris humeral spacer, which provide a 135 degree angle for articulation with the previously cleared glenospheres and humeral cups (K150488 Humelock II® Reversible Shoulder System and K162455 Humelock Reversed® Shoulder System) when used in a reverse shoulder construct.

The Humeris Shoulder System can be used in either an anatomic or a reverse configuration and includes both cementless and cemented variants of the humeral stems.

The Humeris Cementless Humeral Stem is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 with a plasma sprayed commercially pure Titanium (CP Ti) and hydroxyapatite (HA) coating at the distal end.

The Humeris Cemented Humeral Stem is also manufactured from Ti-6Al-4V alloy conforming to ISO 5832-2 with a trapezoidal a polished surface at the distal end.

Intended Use / Indications for Use

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.

Summary of Technologies / Substantial Equivalence

The new Humeris 135 Humeral Cup Eccentric Symmetric and Humeris humeral spacer, are substantially equivalent to the primary predicate in that it is identical to the primary predicate on indications, material, packaging, single use, sterilization, shelf life, pyrogen testing, biocompatibility, compatible components. The subject device, Humeris 135 Humeral Cup and humeral spacer, are added to the cleared Humeris Shoulder System and is a design modification of the currently cleared humeral cup, does not raise different questions of safety and effectiveness and is substantially equivalent to the primary predicate.

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 Humeris135 Shoulder System 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 Humeris 135 Shoulder System to the predicate device.

Summary

Based upon the risk assessment and pre-clinical testing to characterize device performance, substantial equivalence to the predicate device is demonstrated. The Humeris 135 Shoulder System is substantially equivalent based upon indications, design, material, packaging, single use, sterilization, shelf life. The Humeris 135 Shoulder System is expected to be as safe, as effective, and perform as well as the legally marketed predicate device.