FX Shoulder USA, Inc. July 15, 2020
Kathy Trier
VP Regulatory, Quality, Clinical, Compliance
13465 Midway Road,
Suite 101
DALLAS, TX 75244

Re: K191146
Trade/Device Name: Humelock TiN Coated Glenosphere
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: June 29, 2020
Received: July 2, 2020

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,

Michael Owens
Acting 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 *K191146*

Device Name
Humelock TiN Coated Glenosphere

Indications for Use *(Describe)*

The Humelock II Reversible Shoulder System 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.

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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7. 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 ktrier@fxshoulder.com 800.280.0775
Date:	July 13, 2020
Proprietary Name:	Humelock TiN Coated Glenosphere
Common Name:	Shoulder Prosthesis, Reverse Configuration
Product Code(s):	PHX
Classification Name:	21 CFR 888.3660: shoulder joint metal/polymer semi-constrained cemented prosthesis – Class II
Substantially Equivalent Devices:	Primary Predicate: Humelock II Reversible Shoulder System (K150488) Reference Device: LINK® Endo-Model® Knee System with PorEx®; LINK® Sled Knee System with PorEx® (K152431)

Device Description

The Humelock TiN Coated Glenosphere is a new component for Humelock II, Humelock Reversed, and Humeris reversed total shoulder replacement systems. The Humelock TiN Coated Glenosphere has a titanium nitride (TiN) coating, which is applied to the predicate glenosphere made of cobalt chromium molybdenum (CoCr). Compatible components for use with the Humelock TiN Coated Glenosphere to complete the reversed total shoulder replacement construct are the same as those previously cleared compatible components for use with the CoCr glenospheres in the primary predicate device, K150488 and are also

components in K162455 for the Humelock Reversed Shoulder System and K163669 for the Humeris Shoulder, when used for a reverse shoulder construct.

Intended Use / Indications
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.

Summary of Technologies / Substantial Equivalence
The Humelock TiN Coated Glenosphere is substantially equivalent to the primary predicate in that it is identical to the primary predicate on indications, design, dimensions, packaging, single use, sterilization, shelf life, pyrogen testing, biocompatibility, compatible components, instrumentation and surgical technique. It is identical to the primary predicate material CoCr. The change, subject of this 510(k), is to add the titanium nitride (TiN) coating to the surface of the glenosphere, which is substantially equivalent to the technology of coating on the reference device based upon the characterization and testing in accordance with the same scientific methods and standards. Differences between the subject device and the predicate devices do not raise new questions of safety and effectiveness.

Non-Clinical Testing
Biocompatibility testing has been completed in accordance with FDA Guidance titled, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (September 2016).Non-clinical biocompatibility testing is the same as the reference device and includes Acute System Toxicity Study; Cytotoxicity Study; GC/MS Fingerprint Study; Irritation Study; Sensitization Study. Characterization of the TiN coating demonstrates substantial equivalence of the subject device to the coating of the reference device - Bone Implantation Study, 28 Day Muscle Implantation Study; 90Day Muscle Implantation Study are referenced for the subject device. Wear testing under worst case loading and worst case environment with analysis of surface roughness and both UHMWPE and metal particle analysis have been completed.

Mechanical testing for the complete system was previously submitted with the cleared predicate device.

Clinical Testing
Clinical testing was not necessary to determine substantial equivalence of the Humelock TiN Coated Glenosphere to the predicate devices.

Conclusion
The subject device is identical to the primary predicate with the only modification of added TiN coating. The evidence reviewed to demonstrate substantial equivalence includes risk analysis, design controls, biocompatibility, wear properties of the TiN coating, and verification and validation activities to demonstrate that the TiN coating does not increase risk and does

not raise new questions of safety and effectiveness of the Humelock TiN Coated Glenosphere.