



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

April 29, 2020

Re: K193394

Trade/Device Name: Humeral Cup Stability & Humeral Cup 135/145° Stability
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD, KWT
Dated: March 27, 2020
Received: March 30, 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,

For: 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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K193394

Device Name

Humeral Cup Stability & Humeral Cup 135 / 145° Stability

Indications for Use (Describe)

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 metaglène baseplate is intended for cementless use with the addition of screws for fixation.

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 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-rotational 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.

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)

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, Quality, Clinical, Compliance

Date: March 27, 2020

Proprietary Name: Humeral Cup Stability & Humeral Cup 135/145° Stability

Common Name: Shoulder Prosthesis, Reverse Configuration

Product Code(s): PHX, HSD, KWT

Classification Name: 21 CFR 888.3660: shoulder joint metal/polymer semi-constrained cemented prosthesis – Class II
21 CFR 888.3690 shoulder joint humeral (hemishoulder) metallic uncemented prosthesis – Class II
21 CFR 888.3650: shoulder joint metal/polymer nonconstrained cemented prosthesis – Class II

Substantially Equivalent Devices:

Primary Predicate:
Humelock II Reversible Shoulder System (K150488)
Humelock Reversed Shoulder System (K162455)
Humeris Shoulder System (K163669)
32mm Glenosphere and Cups (K192206)

Reference Device:
Delta Xtend™ Shoulder System (K062250).

Device Description

The Humeral Cup Stability and the Humeral Cup 135 / 145° Stability are components that are added to the Humelock II Reversible Shoulder System, the Humelock Reverse Shoulder and Humeris Shoulder, when used as a reverse shoulder replacement. The Humeral Cup and the

Humeral Cup 135 / 145°, Mobility and Standard, were previously cleared for use in the U.S. in the Humelock II Reversible Shoulder System (K150488), and included as compatible components in the Humelock Reversed Shoulder System (K162455) and the Humeris Shoulder (K163669), when used for a reversed total shoulder construct. The 32mm Glenosphere and Cups were added to the reverse shoulder systems in K192206. These reverse total shoulder systems are used in patients with a non-functional rotator cuff and have an inverted articulation such that the ball of the articulation is on the glenoid side and the mating humeral cup is part of the humeral side of the construct, which includes either a cemented or cementless humeral stem. Depending on the humeral stem used, the humeral cup may be fixed to the humeral stem using a 135 / 145° Reverse Adapter. All mating components specific to each system are described in the respective cleared 510(k) submissions.

The predicate humeral cups, the Humeral Cup and the Humeral Cup 135 / 145°, are one-piece constructs consisting of a pre-assembled Ti-6Al-4V alloy shell (ISO 5832-3) and a UHMWPE insert (ISO 5834-1 and ISO 5834-2). Both humeral cups are available in 32mm, 36mm and 40mm to articulate with the glenosphere of the same size (K150488) and come in heights of +3mm, +6mm, and +9mm.

The predicate humeral cups vary in depth providing different amounts of constraint and articulation. This submission is for the Stability variant of the Humelock Reverse Humeral Cup and 135 / 145° Humelock Reverse Humeral Cup and is a component added to the Humelock II Reversible Shoulder System (K150488), Humelock Reversed Shoulder System (K162455) and the Humeris Shoulder (K163669), when used for a reversed total 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 metaglène baseplate is intended for cementless use with the addition of screws for fixation.

The Humelock Reversed 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 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-rotational 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.

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 Stability variant of the Humeral Cup and Humeral Cup 135 / 145° is identical to the primary predicate humeral cups, Mobility and Standard, in intended/indications for use, fundamental scientific technology of the device, material, function, manufacturing processes, shelf life, sterilization, packaging, Instructions for Use, and Surgical Technique. The Stability variant of the humeral cups is similar in design to the predicate humeral cups in that the only modification is in the depth of the cup. The depth of the Stability cup variant is similar in depth to the retentive cup included as the reference device. Based upon these similarities, the Stability variant of the Humeral Cup and Humeral Cup 135 / 145° is substantially equivalent to the predicates.

Non-Clinical Testing

Non-clinical evidence reviewed to demonstrate substantial equivalence includes a comparison of the Stability variant of the Humeral Cup and the Humeral Cup 135 / 145° to the primary predicate humeral cups with respect to the designs, intended/indications for use, fundamental scientific technology of the device, material, function, manufacturing processes, shelf life, sterilization, packaging, Instructions for Use, and Surgical Technique. It is similar to the reference device.

Mechanical testing to ASTM F2028-2017 and range of motion analysis in comparison to the legally marketed predicate devices demonstrates that the Stability variant of the Humeral Cup

and Humeral Cup 135 / 145° is substantially equivalent and does not raise new questions of safety and effectiveness.

Clinical Testing

Clinical testing was not necessary to determine substantial equivalence of the Humeral Cup Stability 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 predicate submitted here, the Humeral Cup Stability and the Humeral Cup 135 / 145o Stability are expected to be as safe, as effective, and perform as well as the legally marketed device predicate.