



October 8, 2019

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

Re: K192206

Trade/Device Name: 32mm Glenosphere and Humeral Cup
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: August 12, 2019
Received: August 14, 2019

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

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K192206

Device Name

32mm Glenosphere and Humeral Cup

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 metaglene 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.

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

Date: August 12, 2019

Proprietary Name: 32mm Glenosphere and Humeral Cup

Common Name: Reverse Shoulder Prosthesis

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 (hemi-shoulder) metallic uncemented prosthesis – Class II
21 CFR 888.3650: shoulder joint metal/polymer non-constrained cemented prosthesis – Class II

Substantially Equivalent Devices:

Primary Predicate:
Humelock II Reversible Shoulder System (K150488)
Humelock Reversed Shoulder System (K162455)
Humeris Shoulder System (K163669)

Reference Device:
DJO Surgical Reverse® Shoulder Prosthesis (RSP) (K092873)

Device Description

The 32mm Glenosphere and Humeral Cup are new components for Humelock II Reversible Shoulder System, Humelock Reversed, and Humeris Shoulder, when used for a reverse shoulder construct. Compatible components for use with the 32mm Glenosphere and Humeral Cup are the same as those previously cleared compatible components for use with the 36mm and 40mm glenospheres in the primary predicate device, K150488 Humelock II Reversible Shoulder System, K162455 Humelock Reversed Shoulder System, and K163669 Humeris Shoulder System, 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.

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 32mm Glenosphere and Humeral Cup are substantially equivalent to the primary predicate in that they are identical to the primary predicate on indications, design, material, packaging, single use, sterilization, shelf life, pyrogen testing, biocompatibility, compatible components, instrumentation and surgical technique. They are similar to the reference predicate in size of components and are a smaller sized components added to the product range for the primary predicate. The change, subject of this 510(k), is to add the 32mm Glenosphere and Humeral Cup to the product range. Differences between the subject device and the predicate devices do not raise new questions of safety and effectiveness.

Non-Clinical Testing

The 32mm Glenosphere and Humeral Cup are of the same design and materials as the previously cleared 36mm and 40mm glenospheres and humeral cups. Mechanical testing for the complete system was previously submitted with the cleared predicate device. Engineering analysis and range of motion analysis was also completed.

Clinical Testing

Clinical testing was not necessary to determine substantial equivalence of the 32mm Glenosphere and Humeral Cup to the predicate devices.