DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 17, 2017

Fx Solutions
Cheryl Hastings
Official Correspondent
1663 Rue De Majornas
Viriat, 01440 FR

Re: K162455
Trade/Device Name: Humelock Reversed Shoulder
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: December 15, 2016
Received: December 16, 2016

Dear Cheryl Hastings:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K162455

Device Name: Humelock Reversed Shoulder

Indications for Use:

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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Prepared:	December 15, 2016
Submitter:	Fx Solutions 1663 Rue de Majornas Viriat, France 01440
Contact:	Jean-Jacques Martin +33 4 74 55 35 55 www.fxsolutions.fr
Proprietary Name:	Humelock Reversed Shoulder
Common Name:	Reverse Shoulder Prosthesis
Classification Names:	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis; Class II 21 CFR 888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis.
Product Codes:	87/PHX, 87/HSD
Substantially Equivalent Devices:	Fx Solutions Humelock II Reversible Shoulder, K150488 Tornier Aequalis Reversed Shoulder Prosthesis, K100142, K082120, K030941

Device Description:

The Humelock Reversed Shoulder is a total shoulder prosthesis designed for use in patients with a non-functional rotator cuff. The articulation of this design is inverted compared to a traditional total shoulder prosthesis. The reverse shoulder is designed so that the ball of the articulation is on the glenoid side and the mating cup fits into the humeral stem. The components of the system include a glenoid baseplate, standard and locking bone screws, optional baseplate post extensions, centered and eccentric glenospheres with and without central screws, humeral cups, cementless and cemented humeral stems, optional cortical bone screws, an optional humeral spacer, an optional anti-rotation spoiler and an optional taper adapter for use in hemi-shoulder replacement.

The Humelock glenoid baseplate has a round base with a central, cannulated post and four peripheral, threaded screw holes. The outer edges of the baseplate are tapered to lock with the glenosphere component.

The glenoid baseplate is used with 4.5mm standard or locking bone screws for added stability. The bone screws are available in lengths from 20 – 50mm in 5mm increments.

Optional post extensions are available to extend the central post of the baseplate and provide additional anchoring in cases with poor bone quality. The post extensions are available in 6mm and 10mm lengths. When used, the post extensions screw into the baseplate post.

The glenoid baseplate, standard and locking screws, and post extensions are manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3. The backside of the baseplate and the post extensions are coated with a plasma sprayed CP Titanium and Hydroxyapatite coating.

The Humelock Reversed Glenosphere is available in 36 and 40 mm diameter sizes in centered and eccentric styles. The eccentric glenospheres are designed to be offset from the center of the glenoid baseplate. All glenospheres have a 10º tilt. Although not physically tilted, the curvature of the glenosphere extends 10º beyond the equator of a hemisphere. This additional articular surface lateralizes the center of rotation to help reduce the potential for scapular notching by the humeral cup. All glenospheres mate with the glenoid baseplate via a taper lock; the glenosphere incorporates a female taper while the edges of the baseplate form a male taper. The glenospheres are also available with an optional central, cannulated screw. This screw can be threaded through the central post of the baseplate for additional security.

The glenospheres are manufactured from Co-Cr-Mo conforming to ISO 5832-12. The glenosphere screw is manufactured from Ti-6Al-4V conforming to ISO 5832-3.

The humeral cups are one-piece constructs consisting of a pre-assembled Ti-6Al-4V alloy shell and a UHMWPE insert. A 24mm diameter tapered post on the inferior surface of the shell locks into the female taper on the superior surface of the humeral stem. The humeral cups are available in 36mm and 40mm diameters and in standard and mobility styles. The standard cups offer a slightly deeper articular surface to provide additional constraint while the mobility cups are not as deep to provide slightly less constraint. The humeral cups are available in heights of +3mm, +6mm and +9mm.

If additional height of the humeral articulation is needed, a +9mm humeral spacer can be used between the humeral stem and the humeral cup. The +9mm humeral spacer adds 9mm of height resulting in construct heights of +12mm, +15mm and +18mm. The spacer has a 24mm male taper that mates with the humeral stem and a 24mm female taper that mates with the humeral cup.

The humeral cups are manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 and UHMWPE conforming to ISO 5834-1 and ISO 5834-2. The +9mm humeral spacers are manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3.

The Humelock Reversed Shoulder includes both cementless and cemented humeral stems. The cementless humeral stems are available in diameters 8 to 16 mm. The distal end is cylindrical with a grit blasted surface and two unthreaded screw holes oriented in the medial/lateral direction. Bone screws can be used to provide additional early fixation and stability of the stem. Cortical bone screws are available in lengths from 18 – 40mm in 2mm increments. The proximal portion of the cementless humeral stem has a plasma sprayed CP Titanium and Hydroxyapatite coating.

Cemented stems are available in diameters 6 to 14 mm. The distal end of the cemented humeral stem is trapezoidal with a polished surface. The cementless and cemented humeral stems incorporate a 24mm diameter female taper for attachment of compatible components.

Both the cementless and cemented stems are compatible with an optional spoiler, which can be attached to the lateral side of the stem to provided additional resistance to rotation. The spoiler is fixed to either stem using an M6 hex screw.

The spoiler and hex screw are manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3.

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, the Humelock Reversed cementless and cemented stems can be used with an eccentric taper adapter and 50, 52 or 54mm eccentric humeral heads for conversion to an anatomic shoulder hemi-arthroplasty. The taper adapter has a 24mm male taper to mate with the humeral stem and a 10mm male taper to mate with the humeral head. The taper adapter is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3. The eccentric humeral heads are manufactured from wrought Co-Cr-Mo conforming to ISO 5832-12.

Intended Use / Indications:

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.

Summary of Technologies/Substantial Equivalence:

The Humelock Reversed Shoulder is substantially equivalent to the predicate device in regards to its intended use and indications, materials, design and sizes. Differences between the subject device systems and the predicate device systems do not raise new types of safety and effectiveness questions.

Non-Clinical Testing:

Range of motion analysis, stem /spacer / humeral cup construct fatigue testing, post-fatigue disassembly testing and torsional fatigue testing of the spoiler were conducted. The results of these tests indicate that the performance of the Humelock Reversed Shoulder is adequate for its intended use. Pyrogenicity testing was conducted and the Humelock Reversed Shoulder met a recommended limit of <20 EU/device construct.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence of the Humelock Reversed Shoulder to the predicate devices.