JUL 2 8 2014

510(k) Summary

Prepared On:	June 23, 2014
Applicant / Manufacturer:	Fx Solutions 1663 rue de Majornas 01440 Viriat France
Contact:	Jean-Jacques Martin +33 4 74 55 35 55 www.fxsolutions.fr
Proprietary Name:	Humelock II Cemented Shoulder System
Common Name:	Total and Hemi-Shoulder Replacement System
Classification Names:	21 CFR 888.3650: Shoulder joint metal/polymer non constrained cemented prothesis, Class II 21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis, Class II
Product Codes:	KWT, HSD
Substantially Equivalent Devices:	K123814 – Humelock II Cemented Shoulder System K994392 - Tornier Aequalis Shoulder Fracture System

Device Description:

The Humelock II Cemented Shoulder System is a total and hemi-shoulder prosthesis consisting of a humeral stem, a humeral head, a double taper connector, and, when used for total shoulder replacement, a glenoid component.

The humeral stem is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 and is available in diameters of 6-15mm. The humeral stem incorporates a female taper for attachment of the double taper connector, which connects to the humeral head.

The double taper connector is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3. One size is available and is compatible with all sizes of humeral stems and humeral heads.

The humeral head is manufactured from wrought Co-Cr-Mo alloy conforming to ISO 5832-12 and is available in diameters of 39 – 50mm in centered and offset styles. A female taper allows attachment to the double taper connector, which connects to the humeral stem.

The glenoid component is manufactured from ultra high molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2. It is available in sizes extra small, small, medium, and large. The glenoid component features two pegs for cemented fixation to the glenoid bone. Each peg contains a radiopaque marker manufactured from tantalum conforming to ASTM F560.

The current submission adds bone graft cutting and manipulating instruments and graft trials to the Humelock II Shoulder System.

Bone graft cutting and manipulating instruments and graft trials may be used to cut bone graft from the humeral head and position it around the humeral stem. The bone graft can be used to help position and consolidate the tuberosities in cases with proximal bone loss.

Intended Use / Indications:

The Humelock II Cemented Shoulder System is indicated for use in total and hemi-shoulder replacement to treat:

1. Proximal humeral fractures
2. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
3. 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).

The humeral stem and glenoid components of the Humelock II Cemented Shoulder System are intended for cemented use only.

Summary of Technologies/Substantial Equivalence:

Substantial equivalence of the Humelock II Cemented Shoulder Prosthesis to the predicate devices is based on comparisons of indications, intended use, materials, and design.

Non-Clinical Testing:

Characterization of the colorant used in the bone graft trial instruments is provided in a device master file and is referenced in this submission. Mechanical testing of the Humelock II Cemented Stem, the Humelock glenoid and the modular connections between components was provided previously.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Humelock II Cemented Shoulder System and the predicate shoulder systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 28, 2014

Fx Solutions
Mr. Jean-Jacques Martin
1663 rue de Majornas
01440 Viriat
France

Re: K140071
Trade/Device Name: Humelock II Cemented Shoulder System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, HSD
Dated: June 26, 2014
Received: June 26, 2014

Dear Mr. Martin:

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" (21CFR 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 yours,

Lori A. Wiggins

for
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): K140071

Device Name: Humelock II Cemented Shoulder System

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Prescription Use X (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices