3. 510(k) Summary

Prepared On:	March 18, 2013
Applicant / Sponsor:	Fx Solutions 1663 rue de Majornas 01440 Viriat France
Manufacturer:	Compagnie Financière & Médicale 13 Bd Victor Hugo 01000 Bourg En Bresse France
Contact:	Jean-Jacques Martin +33 4 74 55 35 55 www.fxsolutions.fr
Proprietary Name:	Humelock II Cementless Shoulder System
Common Name:	Hemi-Shoulder Replacement System
Classification Names:	21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis, Class II
Product Codes:	HSD
Substantially Equivalent Devices:	K992525 - Acumed Modular Shoulder System K111097 – Fx Solutions Humelock Cemented Shoulder Prosthesis K060874 – DePuy Global AP Shoulder System K103835 - Howmedica Osteonics ReUnion TSA System

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Device Description:

The Humelock II Cementless Shoulder System is a hemi-shoulder prosthesis consisting of a humeral stem, a humeral head, a double taper connector, cortical bone screws and an

optional protector and hex screw to prevent bone ingrowth into the threaded hole in the proximal stem.

The humeral stem is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3. The distal end of the humeral component is cylindrical with a grit blasted surface and two unthreaded screw holes oriented in the anterior / posterior direction for fixation using bone screws.

The proximal portion of the humeral component has a plasma sprayed commercially pure Titanium (CP Ti) coating and a hydroxyapatite (HA) coating. A hole in the proximal portion of the humeral component allows attachment to instrumentation designed to provide correct positioning (height and retroversion) of the implant. The humeral stem is available in sizes 8 - 15.

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 double taper connector has a male taper on each end and is used to connect the humeral head to the humeral stem. An impactor / extractor hole is incorporated into the proximal end of the connector.

The humeral head is manufactured from wrought Co-Cr-Mo alloy conforming to ISO 5832-12 and is available in diameters of 39 – 54mm in centered and offset styles. The offset of the taper allows the head to be rotated relative to the cut surface of the humerus to provide optimal coverage of the bone. A female taper allows attachment to the double taper connector, which connects to the humeral stem.

The cortical bone screws are manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 and are available with a diameter of 4.5mm in lengths of 18 – 40mm in 2mm increments.

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

Intended Use / Indications:

The Humelock II Cementless Shoulder System is indicated for use in hemi shoulder replacement for fractures of the proximal humerus. The Humelock II Cementless Humeral Stem is intended for use with two cortical screws and is intended for cementless use only.

Summary of Technologies/Substantial Equivalence:

Substantial equivalence of the Humelock II Cementless Shoulder Prosthesis to the predicate devices is based on a comparison of indications, intended use, materials, design and sizing, and mechanical testing.

Non-Clinical Testing:

Mechanical testing was conducted to demonstrate the fatigue strength of the humeral stem and the stability of the modular connection between the double taper connector and the humeral stem. Pull off testing of the humeral head from the taper was conducted previously. Characterization data was provided for the CP Titanium plasma spray coating and the hydroxyapatite coating.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Humelock II Cementless 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

November 9, 2013

Fx Solutions
Mr. Jean-Jacques Martin
1663 Rue De Majornas
01440 Viriat
France

Re: K130759
Trade/Device Name: Humelock II Cementless Shoulder System
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: October 3, 2013
Received: October 8, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

for Erin I. Keith

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

Enclosure

2. Indications for Use

510(k) Number (if known): K130759

Device Name: Humelock II Cementless Shoulder System

Indications for Use:

The Humelock II Cementless Shoulder System is indicated for use in hemi shoulder replacement for fractures of the proximal humerus. The Humelock II Cementless Humeral Stem is intended for use with two cortical screws and is intended for cementless use only.

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