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

Fx Solutions
% Mr. Frank Ferguson
CEO
Ferguson Medical International Device Consultants LLC
332 Laskin Road, Suite 437
Virginia Beach, Virginia 23451

August 27, 2015

Re: K143721
Trade/Device Name: PRCT2
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: July 29, 2015
Received: July 31, 2015

Dear Mr. Ferguson:

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 yours,

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: K143721

Device Name: PRCT2

Indications For Use:

PRCT2 is indicated for use in fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus.

Prescription Use ___XX__ (21 CFR 801 Subpart D) 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)

# 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Fx Solutions PRCT2 device.

DATE PREPARED: 17 August 2015

## APPLICANTS NAME AND ADDRESS:

Fx Solutions
Attn: Jean-Jacques Martin
1663 rue de Majornas
01440 Viriat
France
Phone: +33 474 55 35 55; FAX: +33 474 52 44 01
jjmartin@fxsolutions.fr

## APPLICANTS CONTACT PERSON IN THE USA:

Ferguson Medical International Device Consultants LLC
Attn: Frank Ferguson, CEO
332 Laskin Road
Suite 437
Virginia Beach, VA 23451
Phone: 757.286.4383; FAX: 801.749.0451
frankf@fergusonmedical-idc.com

## DEVICE NAME:

Trade Name: PRCT2
Common Name: Bone plates and screws
Classification Name: 21CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories

21CFR 888.3040 Smooth or threaded metallic bone fixation fastener

Product Code: HRS: Plate, Fixation, Bone
HWC: Screw, Fixation, Bone

**LEGALLY MARKETED DEVICES TO WHICH FX SOLUTIONS IS CLAIMING SUBSTANTIAL EQUIVALENCE:**

Device Names: Synthes (USA) 3.5mm LCP Periarticular Proximal Humerus Plates (K082625), Internal Fixation Systems, Inc. IFS Bone Plates, Screws, and Washers (K110086)

**DEVICE DESCRIPTION:**

The PRCT2 is a system of plates and screws intended to be used in the fixation of fractures of the humerus. PRCT2 consists of 5 components:

1. Humeral Plates
2. Diaphyseal Plates
3. Screws (Locking and Standard)
4. Trials
5. Instruments

All implants and trials in the PRCT2 system are manufactured from medical grade titanium alloy (TA6V ELI) according to ISO 5832-3.

**INTENDED USE:**

PRCT2 is indicated for use in fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus.

**SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES:**

The components of the Fx Solutions PRCT2 device are offered in the same general range of sizes and shapes of the predicate devices. The materials used for the Fx Solutions device are the same as that used to manufacture the predicates.

**PERFORMANCE DATA:**

The mechanical properties of the Fx Solutions PRCT2 device were tested in accordance with ASTM F382-99, Standard Specification and Test Method for Metallic Bone Plates, and ASTM F543-13, Standard Specification and Test Method for Metallic Bone Screws.

The Fx Solutions device was mechanically tested side-by-side against the predicate device. The test results show equivalence in terms of mechanical strength, therefore substantially equivalent.

**CONCLUSION:**

Based upon the testing and comparison to the predicate device, the Fx Solutions PRCT2 device has the same intended use and similar technological characteristics. The device performs as intended and does not raise any new safety or effectiveness issues, and is therefore substantially equivalent to the predicate devices.