

MAR 12 2012

SECTION 5: 510(K) SUMMARY**Summary of Safety and Effectiveness information****EnHatch Orthopaedics Patient Optimized Humeral Fracture System****Regulatory authority:** Safe Medical Devices Act of 1990, 21 CFR 807.92**1) Device name****Trade name: EnHatch Orthopaedics Patient Optimized Humeral Fracture System****Common name: Proximal Humeral Fracture Plate and Screws****Classification Number/ Classification name/Product code:**

Single/multiple component metallic bone fixation appliances and accessories are class II devices under 21 CFR 888.3030 (product code HRS) and are classified by the Orthopedic Devices Panel.

Smooth or threaded metallic bone fixation fasteners are class II devices under 21 CFR 888.3040 (product code HWC) and are classified by the Orthopedic Devices Panel.

2) Submitter**EnHatch Orthopaedics, LLC**

160 Chubb Avenue, Suite 204

Lyndhurst, NJ 07071

Registration Number: See page 11**3) Company contact****Michael Phipps**

Regulatory affairs

160 Chubb Avenue, Suite 204

Lyndhurst, NJ 07071

Phone: 201-377-9129

mhipps@EnHatch.com

4) Classification**Device class:** Class II**Classification panel:** Orthopedic**Product code:** HRS, HWC**5) Legally Marketed Device to which Equivalence is Claimed:**

- Synthes LCP Proximal Humerus Plate: K011815

- Synthes 3.5 mm LCP Periarticular Proximal Humerus Plates: K082625
- Synthes Small Fragment Dynamic Compression Locking (DCL) System: K000684

6) **Device description**

The EnHatch Orthopaedics Patient Optimized Humeral Fracture System is a system of pre-contoured fracture plates, screws, and instrumentation for the repair of fractures of the proximal Humerus. The plates are designed to fit the natural anatomy of the proximal Humerus and include 3 sizes, different components for left and right Humeri, and plates designed to fit in different positions on the humerus. The proximal portions of the plates accept 3.5 mm locking screws for fixation of head, tuberosity, and shaft fragments to the plate. The distal portions of the plates accept 3.5 mm cortex compression screws which hold the plate construct to the humeral shaft.

EnHatch Orthopaedics Patient Optimized Humeral Fracture System Plates and Screws will be sold non-sterile. They are packaged and shipped in comprehensive trays that allow for secure transportation and on site sterilization. Products used for replenishment will be shipped, non-sterile, in a protective package (poly bag or tube).

7) **Materials**

- All EnHatch Patient Optimized Humeral Fracture System Plates and Screws are made from 316L Stainless Steel per ASTM F138 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants.

8) **Indications for Use**

- The EnHatch Orthopaedics Patient Optimized Humeral Fracture System is indicated for fractures, fracture dislocations, osteotomies, and non-unions of the proximal Humerus, particularly in osteopenic bone.

9) **Summary of technologies**

- The technological characteristics (material, design, sizing, indications) of the EnHatch Orthopaedics Proximal Humeral Fracture plates and screws are similar or identical to the cited predicate devices.

10) **Summary of Non-clinical testing**

Non-clinical mechanical testing was not necessary to determine substantial equivalence between the EnHatch Orthopaedics Patient Optimized Humeral Fracture System and the cited predicate devices.

- For the plates, Finite Element Analysis was used to compare the strength of each EnHatch Plate with a Synthes LCP plate.
- For the screws, a qualitative comparison to the Synthes predicate was done.

Results from these analyses provided with the 510(k) demonstrate that the EnHatch Orthopaedics Patient Optimized Humeral Fracture System are substantially equivalent to the identified predicate devices and will be safe for clinical use.



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

EnHatch Orthopaedics, LLC
% Mr. Michael Phipps
Chief Product Officer
160 Chubb Avenue, Suite 204
Lyndhurst, New Jersey 07071

MAR 12 2012

Re: K112663

Trade/Device Name: EnHatch Orthopaedics Patient Optimized Humeral Fracture System

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: February 21, 2012

Received: February 21, 2012

Dear Mr. Phipps:

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

Page 2 - Mr. Michael Phipps

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,



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

Enclosure

SECTION 4: INDICATION FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K112663

Device Name: EnHatch Orthopaedics Patient Optimized Humeral Fracture System

Indications for Use

- The EnHatch Orthopaedics Patient Optimized Humeral Fracture System is indicated for fractures, fracture dislocations, osteotomies, and non-unions of the proximal Humerus, particularly in osteopenic bone.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112663