K102156 *1/2

510(k) SUMMARY

SEP 30 2010

Submitter Information

Submitter's Name:	OrthoHelix Surgical Designs, Inc.
Address:	1065 Medina Rd, Suite 500 Medina, Ohio 44256
Contact Person:	Derek Lewis
Telephone Number:	330-869-9562
Fax Number:	330-247-1598
Prepared By:	Rebecca DiLiberto and Amanda Martin
Date Prepared:	8/27/2010

Device Information

Trade Name:	MaxLock Extreme® System Distal Radius Plates and Screws
Common Name:	Fixation Plate
Classification Name:	Plate, Fixation, Bone
Device Classification:	Single/multiple component metallic bone fixation appliances (Class II per 21 CFR 888.3030) Panel: Orthopedic, Product Code: HRS
Predicate Device:	The MaxLock Extreme® System Distal Radius Plates and Screws is equivalent to current legally marketed devices.
Material Composition:	Titanium Alloy
Device Description:	The MaxLock Extreme® System Distal Radius Plates and Screws are a modification to the previously cleared Modular Foot System to include site-specific plates and screws for distal radius fixation. The plates are offered in different lengths and sizes. The screws are offered in different diameters and lengths. All implantable components are manufactured from implant grade titanium alloy. The MaxLock Extreme® System Distal Radius Plates and Screws have the same technological characteristics as the predicate devices.
Intended Use:	The MaxLock Extreme® System Distal Radius Plates and Screws are intended for fractures and osteotomies of the distal radius in adult patients.
Substantial Equivalence:	The MaxLock Extreme® System Distal Radius Plates and Screws are equivalent to the OrthoHelix Modular Foot System (K073624) and its subsequent Special 510(k) submission (K100618). In addition, the plates are equivalent to the Hand Innovations Distal Volar Radius Fracture Repair System (K002775) and the screws are equivalent to the Synthes Modular Mini Fragment LCP System (K063049). No new issues of safety and effectiveness have been raised.

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Mechanical testing was conducted to confirm that the MaxLock Extreme® System Distal Radius Plates and Screws are equivalent to the predicate and meet the specified requirements for their intended use. The OrthoHelix plate performed better than the clinically successful legally marketed predicate device. A screw bending moment study was performed to verify that the screws are equivalent to the predicate and meet the specified requirements for their intended use. It is concluded from the static mechanical testing and the screw maximum bending moment study that the devices are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Orthohelix Surgical Designs, Inc.
% Mr. Derek Lewis
1065 Medina Road, Suite 500
Medina, Ohio 44256

SEP 30 2010

Re: K102156
Trade/Device Name: Distal Radius Plating for the MaxLock Extreme® Extremity Plating 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
Dated: August 27, 2010
Received: August 31, 2010

Dear Mr. Lewis:

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.

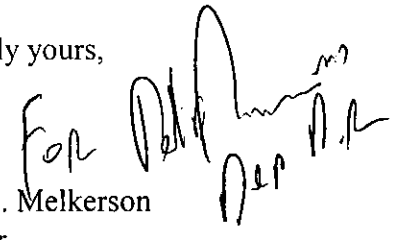
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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" (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,



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

Enclosure

K102156

SEP 30 2010

Indications for Use

510(k) Number (if known): ~~TBD~~ K102156

Device Name: Distal Radius Plating for the MaxLock Extreme® Extremity Plating System

Indications for Use:

The MaxLock Extreme® Distal Radius Plates and Screws are indicated for fractures and osteotomies of the distal radius in adult patients.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm

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

510(k) Number K102156