K093900 (1/2)

FEB 17 2010

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

OrthoHelix Surgical Designs, Inc.
1065 Medina Rd., Suite 500
Medina, Ohio 44256
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Contact Person: Derek Lewis
Vice President of Research and Development

Date Prepared: November 18, 2009

Name of Device

Edgelock Plate System

Common or Usual Name

Fixation Plates

Classification Name

Plate, Fixation, Bone

Predicate Devices

The Edgelock Plate System is substantially equivalent to currently marketed devices.

Intended Use

The Edgelock Plate System is indicated for fractures, fusions and osteotomies of small bones in the hand, wrist, foot and ankle in pediatric and adult patients.

Device Description

The OrthoHelix Edgelock Plate System is a set of metallic, implantable, bone fixation plates. All plates are made from implant grade titanium alloy.

Substantial Equivalence

Finite Element Analysis and mechanical testing confirm that the implants within the Edgelock Plate System are substantially equivalent to its predicate devices, and that it meets the specified requirements for its intended use. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OrthoHelix Surgical Designs, Inc.
% Mr. Derek Lewis
Vice President of Research and Development
1065 Medina Road, Suite 500
Medina, Ohio 44256

FEB 17 2010

Re: K093900
Trade/Device Name: Edgelock Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: December 15, 2009
Received: December 18, 2009

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

Indications for Use

510(k) Number (if known): ~~TBD~~ K093900

Device Name: Edgelock Plate System

Indications for Use:

The OrthoHelix Edgelock Plate System is indicated for fixation of fractures, fusions and osteotomies of the small bones in the hand, wrist, foot and ankle in pediatric and 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)

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

510(k) Number K093900