K061400
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510(k) SUMMARY

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

OrthoHelix Surgical Designs, Inc.
1815 West Market St. Suite #205
Akron, Ohio 44313
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JUN 29 2006

Contact Person:

Lee A. Strnad
Director of Operations & Development
OrthoHelix Surgical Designs, Inc.

Date Prepared:

May 4, 2006

Name of Device

Calcaneal Trauma System

Common or Usual Name

Fixation Plates and Screws

Classification Name

Single/Multiple Component Metallic Fixation Appliances and Accessories

Predicate Devices

DePuy Ace Calcaneal Peri-articular Plate

Intended Use

To stabilize fractures of the calcaneus when internal fixation of either intra-articular or extra-articular fractures is required.

Device Description

The OrthoHelix Calcaneal Trauma System is a set of metallic (titanium alloy), implantable, bone fixation plates and screws. Its' intended function use is to stabilize

fractures of the calcaneus when internal fixation of either intra-articular or extra-articular fractures is required.

The System includes four (4) fixation plates and forty five (45) screws. It also includes various surgical instruments such as drill guides, drill bits and drivers. All screws and plates are made from implant grade titanium, Ti 6Al type 4V ELI per ASTM F 136.

Performance Data

FEA's and hand calculations confirm that the Calcaneal Trauma System is substantially equivalent to its' predicate devices, and that it meets specified requirements for its' intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2006

Orthohelix Surgical Designs, Inc.
c/o Lee A. Strnad
Director of Operations & Development
1815 West Market Street, Suite 205
Akron, Ohio 44313

Re: K061400
Trade/Device Name: Calcaneal Trauma System
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: II
Product Code: HRS, HWC
Dated: May 15, 2006
Received: May 25, 2006

Dear Mr. Strnad:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Zuchus
TOV

Mark Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: Calcaneal Trauma System

Indications for Use:

The Calcaneal Trauma System is indicated for the repair of intra and extra articular fractures of the calcaneus

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)

Barbara Ruckhill for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061402