MAR 7 2006

510(k) SUMMARY

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

OrthoHelix Surgical Designs, Inc.
1815 W. Market Suite 205
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Contact Person: Lee A. Strnad
Senior Development Manager
OrthoHelix Surgical Designs, Inc.

Date Prepared: February 13, 2006

Name of Device

CSS Cannulated Screw System

Common or Usual Name

Cannulated Screws

Classification Name

Screw, Fixation, Bone

Single/Multiple Component Metallic Fixation Appliances and Accessories

Predicate Devices

Howmedica Asnis III Cannulated Screw System (K000080)

Intended Use

The CSS Cannulated Screw System will be indicated for use in long and small bone fracture fixation, which includes the following;

- Fractures of the tarsals and metatarsals

- Fractures of the olecranon, distal humerous
- Fractures of the radius and ulna
- Patella fractures
- Distal tibia and pilon fractures
- Fractures of the fibula, medial malleolus, os calcis
- Tarso-metatarsal and metatarsal phalangeal arthrodesis
- Metatarsal and phalangeal osteotomies
- Osteochondritis dissecans
- Ligament fixation
- Other small fragment, cancellous bone fractures and osteotomies

Device Description

The CSS Cannulated Screw System consists of cannulated screws of various diameters, lengths and thread configurations. The system also includes correspondingly sized washers, the use of which are optional, as well as guide wire and various instruments.

The cannulated screws are self tapping. They are made from made from Titanium Ti-6Al-4V ELI Alloy in conformance with ASTM F-136 Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications.

The CSS System includes (4) different types of washers. These are; Flat Washers, Contoured Washers, Partial Contoured Washers, and Domed Washers. The various styles are intended to offer the surgeon a variety of anatomical fit to the bone in certain applications.

Performance Data

A Finite Element Analysis (FEA) was performed on the CSS Cannulated Screw System, in comparison to its' predicate, the Asnis III. Performance testing was also conducted to confirm the results of the FEA. Results clearly demonstrate that the CSS System is substantially to its' predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 2006

OrthoHelix Surgical Designs, Inc.
C/o Mr. Lee A. Strnad
Senior Development Manager
1815 West Market Street, Suite 205
Akron, Ohio 44313

Re: K060428
Trade/Device Name: CSS Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: HWC, HTN
Dated: February 13, 2006
Received: February 21, 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K060428

Indications for Use

510(k) Number (if known): TBD

Device Name: CCS Cannulated Screw System

Indications for Use: The CSS Cannulated Screw System will be indicated for use in long and small bone fracture fixation, which includes the following;

- Fractures of the tarsals and metatarsals
- Fractures of the olecranon, distal humerous
- Fractures of the radius and ulna
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- Metatarsal and phalangeal osteotomies
- Osteochondritis dissecans
- Ligament fixation
- Other small fragment, cancellous bone fractures and osteotomies

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 General, Restorative, and Neurological Devices

510(k) Number K060428