K082574 1/2

DEC 0 8 2008

510(K) Summary of Safety and Effectiveness
MaxTorque Cannulated Screw System Line Extension

Proprietary Name:	MaxTorque™ Mini Cannulated Screw System
Common Name:	Cannulated Screws
Classification Name and Reference:	888.3040 – Smooth or threaded metallic bone fixation fastener
Regulatory Class:	Class II
Device Product Code:	HWC - Smooth or threaded metallic bone fixation fastener
Contact Information:	Derek Lewis Director of Engineering OrthoHelix Surgical Designs Inc. 1815 W Market Street, 205 Akron, OH 44313 Phone: 330 869-9562 Fax: 330 869-9583 E-Mail: DLewis@orthohelix.com
Summary Date:	December 5, 2008

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Device Description

This special 510(K) submission is a line extension to address modifications to the MaxTorque Cannulated Screw System. This line extension is to add smaller sizes to the system. The additional sizes are - ø 2.5mm, ø 3.0mm, ø 3.2mm, and ø 3.8mm diameter cannulated screws in various lengths. Washers for the ø 3.0mm screws, as well as guide wires and various orthopedic surgical instruments will also be added to the system.

The instruments classified as Class I devices under 21 CFR Parts 888.4300 and 888.4540 (Depth gage for clinical use and Orthopedic manual surgical instruments respectively) are exempt from premarket notification requirements.

Intended Use

The MaxTorque™ Cannulated Screw System is intended for fracture fixation of small and long bones.

Indications

The MaxTorque™ Cannulated Screw System is indicated for use in long and small bone fracture fixation, which includes but not limited to the following:

- Fractures of the tarsals and metatarsals
- Fractures of the olecranon, distal humerus
- Fractures of the radius and ulna
- Patellar fractures
- Distal tibia and pilon fractures
- Fractures of the fibula, medial malleolus, or calcis
- Tarso-metatarsal and metatarsal-phalangeal Arthrodesis
- Metatarsal and Phalangeal osteotomies
- Osteochondritis dissecans
- Ligament fixation
- Other small fragment, cancellous bone fractures and osteotomies

Substantial Equivalence

The MaxTorque Mini Cannulated Screw System is substantially equivalent to commercially marketed predicate devices with respect to design, intended use, performance and operational principle as internal fixation components. Predicate systems considered are the MaxTorque Cannulated Screw System (K060428) and Asnis Cannulated Screw System (K000080, and K071092).

The subject MaxTorque™ Mini Cannulated Screws are a modification to the MaxTorque Cannulated Screw System cleared in K060428. Substantial equivalence for the MaxTorque™ Mini Cannulated Screws is based on indications, intended use, and design to the previously cleared CSS Cannulated Screw System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OrthoHelix Surgical Designs, Inc.
% Mr. Derek Lewis
1815 West Market Street, Suite 205
Akron, Ohio 44313

DEC 0 8 2008

Re: K082574
Trade/Device Name: MaxTorque Mini Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: November 4, 2008
Received: November 10, 2008

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.

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.

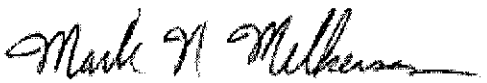
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use Statement

510(K) Number (if known): K082574

Device Name: MaxTorque™ Cannulated Screw System

Indications for Use: The MaxTorque™ Cannulated Screw System is 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 humerus
- Fractures of the radius and ulna
- Patellar fractures
- Distal tibia and pilon fractures
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- Metatarsal and Phalangeal osteotomies
- Osteochondritis dissecans
- Ligament fixation
- Other small fragment, cancellous bone fractures and osteotomies

Prescription Use X **OR** **Over-the-Counter Use** _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K082574