JAN - 3 2014

510(k) SUMMARY

Submitter Information

Submitter's Name:	OrthoHelix Surgical Designs, Inc.
Address:	1065 Medina Rd, Suite 500 Medina, Ohio 44256
Telephone Number:	330-869-9562
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Prepared By:	Liz Altenau
Contact Person:	Brian Hockett or Derek Lewis
Date Prepared:	12/16/2013

Device Information

Trade Name:	OrthoHelix™ Syndesmosis Fixation Devices
Common Name:	Suture Button
Classification Name:	Washer, Bolt Nut
Device Classification:	Single/multiple component metallic bone fixation appliances and accessories Class II per 21 CFR 888.3030 Panel: Orthopedic, Product Code: HTN
Material Composition:	Titanium Alloy and UHMWPE Suture
Device Description:	The OrthoHelix™ Syndesmosis Fixation Devices are implant assembly constructs of metallic buttons and non-absorbable suture intended to aid in the reconstruction of bones in the hand, wrist, elbow, shoulder, foot, and ankle, particularly in the reconstruction of the syndesmosis joint in the ankle and the AC joint in the shoulder. The syndesmosis devices are offered in different configurations, one to be used with and one to be used without a plate. All metallic implant components are manufactured from titanium alloy. All suture implant components are UHMWPE non-absorbable suture.
Intended Use:	The OrthoHelix™ Syndesmosis Fixation Devices are indicated as adjunct fixation in repair involving metaphyseal and periarticular small bone fragments and surrounding soft-tissues where screws are not indicated and as an adjunct in external and intramedullary fixation systems involving plates and rods with fracture braces and casting. Specifically, the Syndesmosis Fixation Devices are intended to provide fixation during the healing process following a syndesmotic trauma such as fixation of ankle syndesmosis disruptions in connection with Weber B and C ankle fractures, as well as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.
Substantial Equivalence:	The new OrthoHelix™ Syndesmosis Fixation Devices are substantially equivalent to the OrthoHelix MaxLock Extreme™ System (K123203), the Teleflex Force Fiber® Polyethylene Non-Absorbable Surgical Suture (K063778), the Arthrex TightRope™ Syndesmosis Device (K043248), the Arthrex TightRope™ Acromioclavicular (AC) Device (K052776), and the Biomet ToggleLoc™ System (K083070). The indications of the OrthoHelix Syndesmosis Fixation Devices differ from some of the predicate devices. The indications of the new OrthoHelix Syndesmosis Fixation Devices do not introduce any new applications or intended uses than the predicates, but rather fit within the scope of use of the predicate devices. Therefore, no new issues of safety and effectiveness are raised with respect to intended indications. The metallic components of the OrthoHelix™ Syndesmosis Fixation Devices conform to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for and Surgical Implant Applications. The implant suture conforms to USP 30- Absorbable Surgical Sutures for Knot Pull Tensile Strength, Needle Attachment and Diameter. In order to demonstrate substantial equivalence to the predicate devices that have the same intended uses, mechanical tensile testing was performed. This testing was used to verify the strength of the implant construct, including the suture and button design and the interaction between the assembly components. The new OrthoHelix devices use a similar mechanism as the Arthrex and Biomet predicate devices: two metallic buttons connected via implantable suture. The surface area, shape, and hole diameters of the buttons differ. The implantable suture for the OrthoHelix differs from the predicates in either size or material. The design differences were verified via mechanical testing to confirm that no new issues of safety and effectiveness have been raised with respect to the strength of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 3, 2014

OrthoHelix Surgical Designs, Incorporated
Mr. Brian Hockett
Director of Engineering
1065 Medina Road, Suite 500
Medina, Ohio 44256

Re: K132733
Trade/Device Name: OrthoHelix™ Syndesmosis Fixation Devices
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: December 16, 2013
Received: December 17, 2013

Dear Mr. Hockett:

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ronald P. Jean -S for

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

Enclosure

Indications for Use

510(k) Number (if known): K132733

Device Name: OrthoHelix™ Syndesmosis Fixation Devices

Indications for Use:

The OrthoHelix™ Syndesmosis Fixation Devices are indicated as adjunct fixation in repair involving metaphyseal and periarticular small bone fragments and surrounding soft-tissues where screws are not indicated and as an adjunct in external and intramedullary fixation systems involving plates and rods with fracture braces and casting. Specifically, the Syndesmosis Fixation Devices are intended to provide fixation during the healing process following a syndesmotic trauma such as fixation of ankle syndesmosis disruptions in connection with Weber B and C ankle fractures, as well as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

Prescription Use ___X____ AND/OR Over-The-Counter-Use_____

(Part 21 CFR 801 Subpart D) (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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices