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510(k) SUMMARY

December 23, 2011

Premarket Notification Number: K112923
Suspension™ Clavicle Fracture Fixation System

Device Classification: Class II (Ref. CFR 21 §888.3030)
Single/multiple component metallic bone fixation appliances and accessories

Sponsor:
Suspension Orthopedic Solutions, Inc
1507 Richie Hwy. Suite 101
Arnold, MD 21012

Sponsor's Representative
Curtis Raymond
Orchid Design
80 Shelton Technology Center
Shelton Connecticut 06484
Telephone 203-922-0105

Device Description:
The subject device consists of the following implantable components:

1. Three sizes of clavicle fracture plate for each shoulder (i.e.—small, medium, and large; each with Left & Right configurations)
2. Eight 2.7mm lengths of non-locking & locking bone screws
3. Eight 3.5mm lengths of non-locking & locking bone screws

Implantable components are included in a carrier case and must be steam sterilized by the hospital or surgical center. These components are intended for re-sterilization, but are for single-use only. All implantable components are composed of stainless steel.

The optionally accompanying Suspension™ Acromioclavicular (AC) Repair System is an internal fixation system consisting of a non-absorbable suture anchor with pre-threaded suture. The metallic suture anchor and metallic accessories are fabricated from 316L stainless steel. Implantable portions of the device are: USP size 5 braided polyethylene suture, coracoid anchor, clavicle set screw, clavicle sleeve extension washer, clavicle sleeve.

Intended Use

The Suspension™ Clavicle Fracture Fixation System can be used for adult patients. The Suspension™ Clavicle Fracture Fixation plates and screws are indicated for fixation of clavicle fractures. For lateral clavicle fractures, the Suspension™ Clavicle Fracture Fixation System may also be used with the Suspension™ Acromioclavicular (AC) Repair System.

Predicate Device(s):

No component of the subject device has been changed in its design, component material, sterilization method, or in any other way from that described in K102095. The sole change to

the device is to allow optional, concurrent use of the Suspension™ Acromioclavicular (AC) System in those instances where lateral clavicle fractures are encountered. Likewise, there have been no changes of any kind made to the Suspension™ Acromioclavicular (AC) System other than allowing its use in conjunction with the subject Clavicle Fixation Plate.

Performance Testing:

The subject device was tested in multiple cadaver shoulders using the proposed method of application. The subject device was compared to the currently marketed Smith & Nephew (K061352). Using an Instron™ device, assessments were made for yield load, stiffness, ultimate load and failure mode. Testing showed that the proposed method of application did not adversely impact the integrity of the construct and substantially equivalent results were observed compared to standard plates.

The subject device was tested in simulated bone. In all instances, the suture component of the subject Acromioclavicular System failed in pull tests before any damage was incurred by the Clavicle Plate. Testing showed that the proposed method of application did not adversely impact the integrity of the clavicle construct.

Engineering analysis has determined that the new connection between the clavicle washer sleeve in the Suspension™ Acromioclavicular Repair System and the subject clavicle plate does not represent a new worst case condition for concerns regarding fretting or corrosion.

Safety Testing:

Biocompatibility for the device was previously demonstrated in K102095. There have been no changes of any kind to the materials used in the device.

Sterility validation testing was previously presented in K102095. There have been no changes of any kind to the methods of sterilization or to the product packaging. Likewise, there have been no modifications to the design of any components of the device such that sterilization might be affected.

Additionally there have been no changes to the design, materials, packaging, sterilization or other features of the optionally accompanying Suspension™ Acromioclavicular (AC) System (K102143).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Suspension Orthopaedic Solutions, LLC
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Mr. Curtis Raymond
Senior Regulatory and Quality Consultant
80 Shelton Technology Center
Shelton, Connecticut 06484

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Re: K112923
Trade/Device Name: Suspension Clavicle Fracture Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC, MBI
Dated: September 30, 2011
Received: October 3, 2011

Dear Mr. Raymond:

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 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): K112923

Device Name: Suspension™ Clavicle Fracture Fixation System

Intended Use

The Suspension™ Clavicle Fracture Fixation System can be used for adult patients. The Suspension™ Clavicle Fracture Fixation plates and screws are indicated for fixation of clavicle fractures. For lateral clavicle fractures, the Suspension™ Clavicle Fracture Fixation System may also be used with the Suspension™ Acromioclavicular (AC) Repair System.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K112923