510(k) Summary

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Suspension™ Acromioclavicular (AC) Repair System
(ref.: K102143)

DEC - 8 2010

December 3, 2010

Submitter/Regulatory Contact:
Curtis Raymond
Orchid Design - 80 Shelton Technology Center - Shelton, CT 06484

Sponsor/Manufacturer:
Suspension Orthopaedic Solutions, LLC
2635 Riva Road, Suite 100 - Annapolis, MD 21401

FDA Establishment Registration Number: Pending

Trade Name, Common Name, Classification:

Device Trade Name: Suspension™ Acromioclavicular (AC) Repair System

Device Common or Usual Names: Non-absorbable Suture Anchor & Accessories

Classification: Class II, 21 CFR 888.3030, JDR (Suture Anchor Accessories) & MBI (Suture Anchor)

Predicate Device:
The substantial equivalence of the AC Repair System is based on similarities in indications for use, design, and material composition to the following currently marketed predicate device:

- AxyaLoop™ Non-absorbable Bone Anchor (K060970)
- AxyaLoop™ Self Tapping Bone Anchor (K052491)
- TeleFlex Force Fiber Blue Co-Braided Polyethylene Suture (K063778)
- LM Anchor (K960825)

Description of the Device:
The Suspension™ Acromioclavicular (AC) Repair System is an internal fixation system consisting of a non-absorbable suture anchor, pre-threaded suture and other attachment accessories that eliminate the need for tying a knot in the suture. The metallic suture anchor and metallic accessories are fabricated from 316L stainless steel. The suture is a USP size 5, co-braided, white/blue polypropylene, non-absorbable suture.

The system consists of the following implantable components that are included in the sterile blister package:

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- USP size 5, co-braided, white/blue polyethylene suture (pre-threaded through the Coracoid Anchor)
- Coracoid Anchor
- Clavicle Set Screw

The following instruments are included in the sterile pack:

- The Torque-Limiting Driver
- The Coracoid Anchor Driver (a 3.0mm hex driver).

The system includes non-sterile implantables included in a carrier tray:

- Clavicle Sleeve Extension Washer
- Clavicle Sleeve

The following instruments are included non-sterile in a carrier tray:

- 5.5mm Drill bit
- 4.0mm Drill Bit
- Suture Tensioner Device

Intended Use:
The Suspension™ Acromioclavicular (AC) Repair System can be used for adult patients. The AC Repair System is indicated for securing suture to bone for acromioclavicular separations and coracoclavicular displacement.

Technological Characteristics:
The subject devices are substantially equivalent to the predicate devices. Both the subject device and predicate devices are provided sterile and are single use. Both devices utilized braided polyethylene suture and manual surgical instruments. The devices are composed medical grade metals and have similar diameters. The axial pull test data was compared and analyzed.

Performance:
The material (316L Stainless Steel) selected is commonly used for orthopedic implants and has a long history of biocompatibility.

The devices have been subjected to recognized consensus standards for these types of devices and perform in a manner equivalent to the predicate devices. The device has been subjected to non-clinical testing including Driving Torque, Pull-Out Strength, Lock Screw Torque, Anchor Torque, and Suture Testing.

Conclusion:
We believe that based on the predicate device comparison and the non-clinical testing performed the subject devices are substantially equivalent to the predicate devices and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Suspension Orthopaedic Solutions, LLC
% Mr. Joseph Azary, Senior Regulatory Consultant
Orchid Design
80 Shelton Technology Center
Shelton, Connecticut 06484

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Re: K102143
Trade/Device Name: Suspension Acromioclavicular Repair System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR, MBI
Dated: November 17, 2010
Received: November 19, 2010

Dear Mr. Azary:

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

(revised)

510(k) Number (if known): K102143

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Device Name: Suspension Acromioclavicular (AC) Repair System

Indications for Use:

The Suspension™ Acromioclavicular (AC) Repair System can be used for adult patients. The AC Repair System is indicated for securing suture to bone for acromioclavicular separations and coracoclavicular displacement.

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 M. Melkerson

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

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