JUL 03 2014

Section 5 510(k) Summary

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson VP, Quality & Regulatory
Date of Preparation:	November 27, 2013
Trade Name:	KISSloc™ Suture System
Common Name:	Plate & Suture System
Device:	Single/multiple component metallic bone fixation appliances and accessories
Classification Regulation:	Regulation Number 888.3030
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	HTN

Device Intended Use

Intended for use in reconstruction (correction) of a hallux valgus deformity by providing for the reduction of 1st metatarsal-2nd metatarsal (IM) angle.

Device Description

The KISSloc™ Suture System is a non-resorbable system consisting of a small Suture Plate, UHMWPE Suture Assembly and Arrow Plate for security. The suture is hooked around the Arrow Plate and passes through the two holes in the plate to form the entire assembly. This implant construct is intended to be used for realignment and stabilization of an underlying skeletal deformity. Ancillary instruments required to aid in insertion of the KISSloc™ Suture System will be provided separately in a sterile disposable package. All implant components will also be provided in a sterile package.

Substantial Equivalency:

The intended use, materials, and application of the Proposed Device are substantially equivalent to the following previously cleared and commercially marketed devices:

- Arthrex Mini TightRope K090107
- Arthrex Mini TightRope Repair Kit K061925

The fundamental scientific technology of the proposed device has not changed relative to the predicate devices:

- Intended for treatment of Hallux Valgus deformity.
- Similar device designs
- Same Titanium and UHMWPE implant materials

In support of this submission, non-clinical mechanical tests and engineering evaluations were performed on the subject device and comparable predicate:

- Peak load to failure (N)
- Number of cycles completed prior to failure
- Displacement slippage per cycle interval
- Finite Element Analysis
- Clinical Evaluations

The test reports demonstrate the Arthrosurface KISSloc™ device was equivalent or outperformed the Arthrex predicate device for the non-clincial mechanical tests conducted.

No clinical data was provided in support of this substantial equivalency.

The results have demonstrated the safety and effectiveness of the KISSloc™ Suture System along with substantial equivalence to the predicate devices. Minor differences in device design and technique were determined not to be critical to the intended use of the device when used as labeled.

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

July 3, 2014

Arthrosurface, Incorporated
Ms. Dawn Wilson
Vice President, Quality and Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K133835
Trade/Device Name: KISSLoc™ Suture System
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: May 30, 2014
Received: June 2, 2014

Dear Dawn Wilson:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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 -S

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

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K133835

Device Name: KISSloc™ Suture System

Indications for Use:

Intended for use in reconstruction (correction) of a hallux valgus deformity by providing for the reduction of 1st metatarsal-2nd metatarsal (IM) angle.

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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices