



Food and Drug Administration
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Fusion Orthopedics, LLC
% J.D. Webb
Regulatory Consultant
The Orthomedix Group, Inc.
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Round Rock, Texas 78681

August 11, 2017

Re: K170624
Trade/Device Name: TalarLift STS
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 8, 2017
Received: August 9, 2017

Dear J.D. Webb:

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" (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 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K170624

Device Name

TalarLift STS

Indications for Use (Describe)

The TalarLift STS arthroereisis implant is designed for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequelae. The TalarLift STS is intended for the following pathological conditions resulting from disease, injury, or other trauma:

- Hypermobile pes valgus;
- Posterior tibial tendon dysfunction;
- Severe pronation;
- Subtalar instability;
- Hypermobile flexible congenital flat foot.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary: TalarLift STS

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	May 9, 2017
Submitted By	Fusion Orthopedics, LLC 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876
Primary Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele e-mail: jdwebb@orthomedix.net
Trade Name	TalarLift STS
Common Name	Subtalar spacer
Classification Name	Screw, fixation, bone
Class	II
Product Code	HWC
CFR Section	21 CFR section 888.3040
Device Panel	Orthopedic
Primary Predicate Device	CSTS Screw, OrthoPro (K093055)
Secondary Predicate Devices	STS Screw, OrthoPro (K032682) HyProCure II, GraMedica (K142534) TALEX™ Subtalar Stabilization System, Vilex, Inc. (K041289) Sub-Talar Lok Implant, Instratek, Inc (K080280)
Reference Predicate Devices	Kangli Pedicle Screw System (K140053 and K142290) HammerTech® Fixation System, Fusion Orthopedics LLC (K161449)
Device Description	The TalarLift STS consists of a threaded implant, designed to be inserted between the posterior and middle facets of the subtalar joint, and corresponding instrumentation to facilitate insertion. The system consists of three configurations, conical, cylindrical, and anatomic. All three devices are manufactured from titanium alloy (Ti-6Al-4V) complying with ASTM F136.
Indications for Use	The TalarLift STS arthroereisis implant is designed for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequelae. The TalarLift STS is intended for the following pathological conditions resulting from disease, injury, or other trauma: <ul style="list-style-type: none"> • Hypermobility pes valgus; • Posterior tibial tendon dysfunction; • Severe pronation; • Subtalar instability; • Hypermobility flexible congenital flat foot.

Materials	Titanium alloy (Ti-6Al-4V - ASTM F136) Stainless steel (ASTM F899) Silicone
Substantial Equivalence Claimed to Predicate Devices	The TalarLift STS is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Non-clinical Test Summary	<p>The following analyses were conducted:</p> <ul style="list-style-type: none"> • FEA was performed to determine worst case for mechanical testing • Static compression test • Insertion / expulsion test • Pyrogenicity was evaluated using the Limulus amoebocyte lysate (LAL) assay. The testing demonstrated that the subject device meets the recommended maximum endotoxin level of 20 EU per device. <p>The results of these evaluations indicate that the TalarLift STS is equivalent to predicate devices.</p>
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Fusion Orthopedics LLC considers the TalarLift STS to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use