



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Wright Medical Technology, Incorporated  
Ms. Tara Conrad  
Regulatory Affair Specialist II  
1023 Cherry Road  
Memphis, Tennessee 38117

May 8, 2015

Re: K150213

Trade/Device Name: Subtalar Spacer System (STS)  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HWC  
Dated: January 21, 2015  
Received: January 30, 2015

Dear Ms. Conrad:

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

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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 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)

K150213

Device Name

Subtalar Spacer System (STS)

Indications for Use (Describe)

The STS screw is indicated for use in treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequela.

- Severely pronated foot;
- Walking intemperance;
- Calcaneal stance position greater than 5°;
- Manually correctable deformities;
- Mid-tarsal breech (arch pain);
- Forefoot varus greater than 10°.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



Headquarters  
Wright Medical Technology, Inc

1023 Cherry Road  
Memphis, TN 38117

901 867 9971  
wmt.com

## 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Subtalar Spacer System (STS).

1. **Submitted By:** Wright Medical Technology, Inc.  
1023 Cherry Road  
Memphis, TN 38117
- Date:** May 13, 2015
- Contact Person:** Tara Conrad  
Regulatory Affairs Specialist II  
Phone: 901-867-4367 Fax: 901-867-4190
2. **Proprietary Name:** Subtalar Spacer System (STS)
- Common Name:** Smooth or threaded metallic bone fixation fastener
- Classification Name and Reference:** 21 CFR 888.3040- Class II
- Device Product Code, Device Panel:** HWC- Orthopedic
3. **Predicate Device:** K032682-Ortho-Pro STS Screw  
K070441-Metasurg Subtalar Implant
4. **Device Description**

The Subtalar Spacer System (STS) a threaded implant designed to be inserted between the posterior and middle facets of the subtalar joint. It is manufactured from Ti-6Al-4V per ASTM F136 and is available in 6 sizes. STS has a center cannula design for use with a guide wire to facilitate proper placement.
5. **Intended Use**

Indications for Use:

The STS implant is indicated for use in treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequela.

  - Severely pronated foot;
  - Walking intemperance;
  - Calcaneal stance position greater than 5°;
  - Manually correctable deformities;

- Mid-tarsal breech (arch pain);
- Forefoot varus greater than 10°.

**6. Technological Characteristics Comparison**

The STS implant and the legally marketed predicate Ortho-Pro STS Screw have identical indications, have the same overall features, and are identical in material. The two differences are:

- 1) Total length
- 2) Pitch

**7. Substantial Equivalence- Non-Clinical Evidence**

Testing rationales were provided to support the substantial equivalence of the subject device and show that no new worst-case devices are introduced in this system. The safety and effectiveness of the STS implant is adequately supported within this premarket notification. Through the analysis of technical characteristics the new devices are substantially equivalent to the predicate devices.

**8. Substantial Equivalence- Clinical Evidence**

N/A

**9. Substantial Equivalence- Conclusions**

The design characteristics of the subject devices do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.