

MAR 17 2009

Summary of Safety and Effectiveness information
Special 510(k) Premarket Notification – Salto Talaris Total Ankle Prosthesis

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1) Device name

Trade name: *Salto Talaris Total Ankle Prosthesis*
Common name: Total Ankle Prosthesis
Classification name: 888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
Mrs Séverine Bonneton
Regulatory affairs Specialist
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
Tel: 00 33 4 76 61 35 00
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e-mail : severine.bonneton@tornier.fr

4) Classification

Device class: Class II
Classification panel: Orthopedic
Product code: 87 HSN

5) Equivalent / Predicate device

Salto Talaris Total Ankle Prosthesis, Tornier, K060544
Alvine Total Ankle Prosthesis (Agility), DePuy, K920802, K020541
Topez Total Ankle Replacement, Topez Orthopedics, Inc., K051023

6) Device description

The goal of total ankle replacement is to restore function and relieve pain. The Salto Talaris Total Ankle Prosthesis is intended to accomplish these goals. The Salto Talaris Total Ankle Prosthesis is a semi-constrained anatomical design, which reproduces the kinematics of the ankle joint.

The Tornier Salto Talaris Total Ankle Prosthesis consists of two mating components: a metal tibial base in association with a conforming polyethylene articulating insert, and a metal talar resurfacing component.



7) Materials

The tibial base and the talar components are manufactured from Cobalt-Chromium alloy according to ISO 5832-4. The polyethylene insert is manufactured from implant grade ultra-high molecular weight polyethylene (UHMWPE) according to ISO 5834-2.

The bone contacting surfaces are coated with titanium plasma spray according to ASTM F1580.

8) Indications

The Salto Talaris Total Ankle Prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

All components are intended for cemented use only.





MAR 17 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tornier
% Ms. Séverine Bonneton
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex
France

Re: K090076

Trade/Device Name: Salto Talaris Total Ankle Prosthesis
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSN
Dated: February 18, 2009
Received: February 20, 2009

Dear Ms. Bonneton:

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.

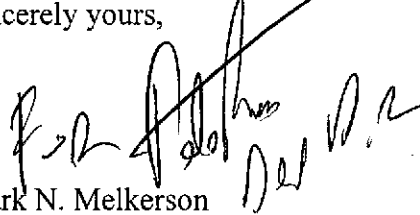
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over a horizontal line.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090076

Device Name: Salto Talaris Total Ankle Prosthesis

Indications For Use:

The Salto Talaris Total Ankle Prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

All components are intended for cemented use only.

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 IF NEEDED)

Concurrence of CDRL Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number

K090076