



August 11, 2016

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Tornier Sas
Séverine BONNETON
Regulatory Affairs Manager, Special Projects
161 rue Lavoisier
38330 Montbonnot Saint Martin
FRANCE

Re: K153452

Trade/Device Name: Salto XT, Salto Talaris
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: July 11, 2016
Received: July 12, 2016

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. 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 Parts 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,

Vincent J. Devlin -S

for

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)

K153452

Device Name

Salto Talaris

Indications for Use (Describe)

The Salto Talaris 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.

Components are intended for cemented use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number (if known)

K153452

Device Name

Salto XT

Indications for Use (Describe)

The Salto XT ankle prosthesis is indicated as a total ankle replacement in revision surgeries only for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

Components are intended for cemented use only.

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)

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TORNIER

Implants Chirurgicaux

Summary of Safety and Effectiveness information *Traditional 510(k) Premarket – Salto XT, Salto Talaris*

Regulatory authority: 21 CFR 807.92

Date prepared: 25 November 2015

1) Device name

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

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

2) Submitter :

TORNIER SAS
 161 rue Lavoisier
 38330 Montbonnot Saint Martin- France
 Registration Number: 3000931034

3) Company contact :

Tornier
 Mrs Séverine BONNETON
 Regulatory Affairs Manager, Special Projects
 161, rue Lavoisier
 38334 Montbonnot Saint-Martin - FRANCE
 Tel: 00 33 4 76 61 35 51 Fax: 00 33 4 76 61 35 59
 E-mail: severine.bonneton@tornier.com

4) Classification

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

5) Equivalent / Predicate device :

Primary predicate:

Salto Talaris, TORNIER, K060544, K090076, K130533.



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S.A.S. au capital de 35 043 008 €
 SIRET : 070 501 275 000 21
 R.C.S. : 070 501 275
 CODE APE : 3250 A

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Implants Chirurgicaux

Reference predicates:

Inbone II Total Ankle System, Wright Medical Technology, Inc, K100886, K103374, K123059, K133585.

Infinity Total Ankle System, Wright Medical Technology, Inc, K123954, K140749

Agility Total Ankle Prosthesis, Depuy, Inc: K020541, K053569, K122395

6) Device description :

The cleared Salto Talaris and the new Salto XT are intended for total ankle replacement. Both are a semi-constrained anatomical design, which reproduces the kinematics of the ankle joint. And both consist of two mating components: a metal tibial base in association with a conforming polyethylene articulating insert, and a metal talar component.

The submission seeks clearance for:

- the addition of new components to the Salto range: the Salto XT (tibial and talar components),
- the addition of a new size and new thicknesses to the cleared range of Salto Talaris tibial inserts.

The tibial inserts are compatible with both Salto Talaris (K060544, K090076, K130533) and the new Salto XT. The new device Salto XT has been designed to be compatible with the cleared and the new Salto Talaris tibial inserts. All Salto XT components are compatible with cleared Salto Talaris components.

7) Materials :

The Salto XT tibial base is manufactured from titanium alloy and the Salto XT talar component is manufactured from chromium cobalt alloy. The Salto XT tibial and talar components are coated with titanium plasma spray.

The Salto Talaris tibial inserts are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE).

8) Indications :

Salto XT:

The Salto XT ankle prosthesis is indicated as a total ankle replacement in revision surgeries only for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

Components are intended for cemented use only.

Salto Talaris:

The Salto Talaris 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.

Components are intended for cemented use only.



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9) Summary of technological characteristics

Main features or system characteristics		Salto XT	Salto Talaris	INBONE II	INFINITY	AGILITY
Materials	Tibial component	Titanium alloy	CoCr alloy	Titanium alloy	Titanium alloy	Titanium alloy
	Tibial Insert	UHMWPE	UHMWPE	UHMWPE	UHMWPE	UHMWPE
	Talar component	CoCr alloy	CoCr alloy	CoCr alloy	Titanium alloy	CoCr alloy
	Coating	Titanium plasma spray	Titanium plasma spray	Titanium plasma spray	Commercially pure Titanium	Commercially pure Titanium
Sizes	Tibial component	4 sizes	4 sizes	9 sizes (right & left)	8 sizes	6 sizes (right & left)
	Tibial insert	5 sizes cleared + 1 new size (right & left)		10 sizes with different thicknesses for each size	8 sizes with different thicknesses for each size	6 sizes (insert / revision / revision +2)
	Talar component	4 sizes (right & left)	4 sizes (right & left)	5 sizes (right & left)	5 sizes	6 sizes (posterior augmented / revision)
Indications for use		Total ankle replacement	Total ankle replacement	Total ankle replacement	Total ankle replacement	Total ankle replacement
Method of fixation		cemented	cemented	cemented	cemented	cemented
Terminal sterilization		Gamma	Gamma	Gamma	Gamma	Gamma
Manufacturer		Tornier	Tornier	Wright Medical Technology, Inc	Wright Medical Technology, Inc	Depuy, Inc
K-number		K153452	K060544 K090076 K130533	K100886 K103374 K123059 K133585	K123954 K140749	K020541 K053569 K122395

The indications for use, materials, method of fixation and sterilization processes for the Salto XT are identical or equivalent to the predicate devices.



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10) Non-clinical testing

The following non-clinical tests were performed:

- **Tibial fatigue** - The aim of the tibial fatigue test is to evaluate the fatigue strength of the Salto XT tibial tray.
- **Insert locking mechanism** - The aim of the insert locking mechanism test is to measure the locking strength of insert and tray assembly.
- **Talar stability with bone**: The aim of talar stability test is to check the talar connection to the bone of the Salto XT.
- **Contact pressure** - The aim of the contact pressure measurement test is to compare the contact pressure profile between the Salto XT talar component and its predicate device.
- **Wear** - The aim of the wear test is to check the resistance of the Salto XT and to compare it to the resistance of the predicate.

The results of these tests demonstrate that the proposed new Salto XT and the new Salto Talaris tibial inserts are equivalent to the predicate devices.

11) Substantial conclusion equivalence

Based upon comparative analysis, substantial equivalence of the new Salto XT and the new Salto Talaris tibial inserts to the predicates can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

- The Salto XT and Salto Talaris inserts are comparable to the predicate devices.
- The Salto XT and Salto Talaris inserts have the same intended use as the cleared predicates and have same/similar indications for use.
- Major technological characteristics are equivalent between the Salto XT, the Salto Talaris inserts and the predicate devices:
 - Equivalence of general features
 - Equivalent materials,
 - Equivalent biomechanical features: mechanical characteristics, congruence of articular surfaces,
 - Equivalent means of fixation
 - Equivalent prosthetic dimensions

Therefore, in light of the above information, the Salto XT and Salto Talaris inserts are found to be equivalent to the predicate devices.



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