K103007

NOV - 9 2010

SECTION 5

Special 510(k) Premarket Notification
October 8 2010
Summary of Safety and Effectiveness information

Tornier Inc. Affiniti Total and Hemi-Shoulder System

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

1) **Device name**

Trade name:	**Affiniti Total and Hemi-Shoulder System** **Affiniti Shoulder System**
Common name:	Shoulder prosthesis, humeral head
Classification name:	Shoulder joint metal/polymer semi-constrained cemented Shoulder joint humeral (hemi-shoulder) metallic uncemented
Classification number:	**888.3660** and **888.3690**

2) **Submitter**

Tornier Inc.
7701 France Ave. S,
Suite 600
Edina, MN 55435
Registration Number: 9100540

3) **Company contact**

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4) **Classification**

Device class:	Class II
Classification panel:	Orthopedic
Product code:	KWS and HSD

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5) **Equivalent / Predicate device**

- Tornier DVO Total and Hemi Shoulder System: K060988

Note:

- The Tornier DVO Total and Hemi Shoulder System (K060988) is presently named Affiniti Total and Hemi-Shoulder System and hereafter will be referred to as such.

6) **Device description**

The sterile **Affiniti Total and Hemi-Shoulder System** is comprised of a :

- Humeral stem,
- Humeral heads in two styles (standard and eccentric)
- Glenoids in two styles (pegged or keeled).

The humeral heads mate on the stems through a locking taper. The humeral heads are highly polished and articulate with the glenoids.

The humeral stems are offered in two versions Non-coated humeral stems and Porous coated humeral stems :

- Non-Porous coated humeral stems and Porous coated humeral stems are offered in two lengths:
  - Standard
  - long

The humeral heads are available in:

- 15 standard sizes
- 10 eccentric sizes
- 8 extended head sizes (Product line addition to K060988 via K073331)

The Glenoid is available in multiple sizes in 2 different configurations(pegged or keeled).

- This submission corresponds to a change made to the **Affiniti Total and Hemi-Shoulder System** (previously cleared in 510(k) K060988), The change correspond to the addition of a porous coated to Humeral stems of the Affiniti Shoulder System.

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7) Materials

Materials include titanium humeral stems (some stems coated with pure titanium); cobalt chrome humeral heads and ultrahigh molecular weight polyethylene glenoids.

8) Indications

The Affiniti™ Total and Hemi-Shoulder System are indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture/dislocations of the proximal humerus; where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

The Affiniti™ Hemi-Shoulder System is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.
3. Rotator cuff tear arthropathy.

Notes:

- Glenoid components are labeled "for cemented use only" and are indicated only for use with bone cement.
- Humeral stems are indicated for press-fit un-cemented use or for use with bone cement.
- This is a single use device.

9) Substantial Equivalence

The modifications made to the proposed Tornier Inc. Affiniti Total and Hemi-Shoulder System were verified and validated by performing:

- **Bench test:**
  - Fatigue testing

- **Porous coating Characterisation and evaluation:**
  - Static Tensile Test
  - Static Shear Test
  - Shear Fatigue Test
  - Bending Fatigue Test
  - Abrasion Resistance Test

The results of those evaluations allow us to conclude that the proposed Tornier Inc. Affiniti Total and Hemi-Shoulder described in this submission does not induce any new or higher risk compared to the predicate device and therefore both device (proposed and predicate) are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Tornier, Inc.
% Mr. Brahim Hadri
Senior Regulatory Affairs Specialist
100 Cummings Center, Suite 444C
Beverly, Massachusetts 01915

NOV - 9 2010

Re: K103007
Trade/Device Name: Affiniti Total and Hemi-Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: October 12, 2010
Received: October 12, 2010

Dear Mr. Hadri:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use K103007

510(k) Number (if known):

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Device Name: Affiniti Total and Hemi-Shoulder System

Indications For Use:

The Affiniti Total and Hemi-Shoulder System are indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
2. Fracture/dislocations of the proximal humerus; where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

The Affiniti Hemi-Shoulder System is also indicated for:
1. Ununited humeral head fractures.
2. Avascular necrosis of the humeral head.
3. Rotator cuff tear arthropathy.

Notes:
- Glenoid components are labeled "for cemented use only" and are indicated only for use with bone cement.
- Humeral stems are indicated for press-fit un-cemented use or for use with bone cement.
- This is a single use device.

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 CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K103007