SECTION 5

510(k) SUMMARY

Summary of Safety and Effectiveness information

Special 510(k) Premarket Notification – Tornier Inc. Latitude Elbow Prosthesis

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

1) **Device name**
   - **Trade name:** ***Latitude Elbow Prosthesis***
   - **Common name:** Elbow Prosthesis
   - **Classification name:** Elbow joint metal/polymer semi-constrained cemented prosthesis
     Elbow joint metal/polymer constrained cemented prosthesis
   - **Classification number:** 888.3160 and 888.3150

2) **Submitter**

Tornier Inc.
3601 West 76th Street
Suite 200
Edina, MN 55435
Registration Number: 9100540

3) **Company contact**

Brahim Hadri
Sr. Regulatory affairs Specialist
100 Cummings Center, Suite 444C,
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4) **Classification**

Device class:	Class II
Classification panel:	Orthopedic
Product code:	JDB and JDC

5) **Equivalent / Predicate device**

Tornier Latitude Elbow Prosthesis, K000003, K011567, K031218, K050848 and K070787

6) Device description

Total Elbow replacement is used to treat a number of clinical conditions such as severe pain or significant disability in degenerative, rheumatoid or traumatic disease of the elbow joint. They are also used in revision procedures where other treatments or devices have failed and treatment of fractures that are unmanageable using other techniques. The usual goal of such surgery is to restore the elbow joint to its best working condition and to reduce or eliminate pain. The Tornier Inc. Latitude Elbow Prosthesis is intended to accomplish these goals. The Tornier Inc. Latitude Elbow Prosthesis is intended for use as a cemented total elbow.

The Tornier Inc. Latitude Elbow Prosthesis is a 3-part system consisting of a humeral, an ulnar and a radial component.The humeral implant is modular and consists in the assembly of various sizes of humeral stem and humeral spool in order to better reproduce the functionality of the natural humerus.
The prosthesis is a non constrained prosthesis and when it is used with the ulnar cap the prosthesis becomes a constrained prosthesis.

The present device submission corresponds to several changes made to the version of the device cleared in the latest 510k K070787.

7) Materials

The humeral stem is available in CoCr alloy. The humeral spool is available in CoCr alloy with a PEEK-OPTIMA polymer insert. The humeral screw is available in stainless steel. The radial components are made of CoCr alloy and UHMWPE. The ulnar assembly has a stem component made of CoCr alloy and a bushing made of UHMWPE.

8) Indications

The *Tornier Inc.* Latitude *Elbow Prosthesis* is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability following the effects of primary or secondary osteoarthtitis and rheumatoid arthritis; correction of functional deformities; revision procedures where other treatments or devices have failed; treatment of fractures that are unmanageable using other techniques.
The *Tornier Inc.* Latitude *Elbow Prosthesis* is intended for cemented use only.

9) Substantial Equivalence

The modifications made to the proposed *Tornier Inc.* Latitude *Elbow Prosthesis* were verified and validated by performing Cadaver evaluations; CAD evaluations; Mechanical bench testing; as well as Sterilization and Packaging validation. The results of those evaluations allow us to conclude that the proposed *Tornier Inc.* Latitude *Elbow Prosthesis* 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 W-O66-0609
Silver Spring, MD 20993-0002

JUN 29 2010

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

Re: K100562
Trade/Device Name: Latitude Elbow Prosthesis
Regulation Number: 21 CFR 888.3160
Regulation Name: Elbow joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDB, JDC
Dated: June 9, 2010
Received: June 11, 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,

for Barbara Brehm

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

Enclosure

K100562

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Indications for Use

510(k) Number (if known):

Device Name: Latitude Elbow Prosthesis

Indications For Use:

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The Tornier Inc. Latitude Elbow Prosthesis is 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 CDRH, Office of Device Evaluation (ODE)

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