K060545

APR 2 1 2006

TORNIER

Implants Chirurgicaux

Summary of Safety and Effectiveness information
510(k) Premarket Notification – Unity Humeral Plate

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

1) Device name

Trade name:	**Unity Humeral Plate**
Common name:	Humeral Plate
Classification name:	Single/multiple component metallic bone fixation appliances and accessories
Classification number:	888.3030

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
Mrs Mireille Lémery
Regulatory affairs Manager
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
Tel: 00 33 4 76 61 38 98
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e-mail : mireille.lemery@tornier.fr

4) Classification

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

5) Equivalent / Predicate device

Synthes LCP Proximal Humerus Plates, Long, K041860
Numelock II System (Lateral Proximal Humerus Plate), Howmedica Osteronics Corporation, K041709

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S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

6) Device description

The Unity Humeral plate is intended to provide a temporary fixation of proximal humerus fractures. It is pre-contoured to fit the anatomical profile of the proximal humerus. The plate combines orientable screws, locking screws and cortical screws to provide compression and angular stable locking.

7) Materials

The humeral plate is made of stainless steel (ISO 5832-1) or low nickel stainless steel (ASTM F2229). The optional wire is made of stainless steel (ISO 5832-1). The associated screws are made of low nickel stainless steel (ASTM F2229).

8) Indications

The Tornier humeral plate is indicated for simple or complex fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2006

Tornier
c/o Mrs. Mireille Lémery
Regulatory Affairs Manager
161, rue Lavoisier – Montbonnot
38334 Saint-Ismier Cedex - France

Re: K060545
Trade/Device Name: Unity Humeral Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: February 27, 2006
Received: March 8, 2006

Dear Mrs. Lémery:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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):

Device Name: Unity Humeral Plate

Indications For Use:

The Tornier humeral plate is indicated for simple or complex fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus.

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 General, Restorative, and Neurological Devices

510(k) Number K060545