JUN 1 9 2001

K011567

Summary of Safety and Effectiveness Information **Special 510(k): Device modification** **Premarket Notification, Section 510(k)**	***Tornier Total Elbow Prosthesis*** **Tornier S.A.**

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

1) Device name

Trade name:	***Tornier Total Elbow Prosthesis***
Common name:	Total Elbow Prosthesis
Classification name:	Elbow joint metal/polymer semi-constrained or constrained cemented prosthesis

2) Manufacturer

Tornier S.A.
B.P. 11 - Rue Doyen Gosse
38330 Saint Ismier - France

3) Classification

§ 888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis.
§ 888.3150 Elbow joint metal/metal or metal/polymer constrained cemented prosthesis.

Classification panel:	Orthopedic
Product code:	87 JDB / 87JDC
Device class:	Class II

4) Device description :

The present device modification submission concerns the evolution of the radial head, which is a part of the *Tornier Total Elbow Prosthesis,* already legally marketed. The humeral and the ulnar component are unchanged.
The radial head is composed of a radial stem and a radial head. The modification consists on the addition of a smaller diameter stem (5 mm) to the previous range of components.
The radial head component remains identical to the cleared device. The assembly of the stem and the radial head is unchanged.
The manufacturing methods, intended use, packaging and sterilization of the subjected device are identical to the predicate device.

5) Indications :

The *Tornier Total Elbow Prosthesis* is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated in the following cases : to relieve severe pain or significant disability in degenerative, rheumatoid or traumatic disease of the elbow joint; correction of functional deformities; revision procedures where other treatments or device have failed; treatment of fractures that are unmanageable using other techniques.
This device is intended for cemented use only.

6) Materials :

Humeral implant components are available in CoCr alloy according to standard ISO 5832-7 or ISO 5832-4.
The ulnar and radial components are made of CoCr alloy according to standard ISO 5832-7 or ISO 5832-4, and UHMWPE according to standard ISO 5834-2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2001

Ms. Irene Gosset
Regulatory Affairs Department
Tornier S.A.
161, Rue Lavoiser
38330 Montbonnot
France

Re: K011567
Trade Name: Tornier Total Elbow Prosthesis
Regulation Number: 888.3160 and 888.3150
Regulatory Class: II
Product Code: JDB and JDC
Dated: May 16, 2001
Received: May 21, 2001

Dear Ms. Gosset:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known): K011567

Device name: ***Tornier Total Elbow Prosthesis***

Indication for use:

The *Tornier Total Elbow Prosthesis* is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated in the following cases : to relieve severe pain or significant disability in degenerative, rheumatoid or traumatic disease of the elbow joint; correction of functional deformities; revision procedures where other treatments or device have failed; treatment of fractures that are unmanageable using other techniques.
This device is intended for cemented use only.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

D Mitchell MD for CMW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011567

Prescription use X OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional format 1-2-96)