AUG 1 5 2001

K012212

Summary of Safety and Effectiveness Information **Special 510(k): Device modification** **Premarket Notification, Section 510(k)**	***Aequalis Shoulder System*** **Tornier S.A.**

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

1) Device name

Trade name:	***AEQUALIS Shoulder System***
Common name:	Total-Shoulder System and Hemi-Shoulder System
Classification name:	- Shoulder joint, metal/polymer semi-constrained cemented prosthesis

2) Manufacturer

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

3) Classification

§ 888.3660 Shoulder joint, metal/polymer semi-constrained cemented prosthesis.

Classification panel:	Orthopedic
Product code:	87 KWS
Device class:	Class II

4) Device description :

The present Device Modification submission corresponds to the addition of humeral heads made from Cobalt-Chromium-Molybdenum Alloy according to the standard ISO 5832-12 to the previous range with the same indications for use already covered by the previous 510(k) clearance. The humeral stem and the glenoid component are unchanged.
The manufacturing methods, intended use, packaging and sterilization of the subjected device are identical to the predicate device.

5) Indications :

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; non-union humeral head fracture; displaced 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult management problems where arthrodesis or resectional arthroplasty are not acceptable.

6) Materials :

The stem is made from Cobalt Chromium alloy according to ISO 5832-4. The humeral head is available in both Cobalt-Chromium alloy according to ISO 5832-7 and ISO 5832-12. The glenoid components are produced from implant grade ultra-high molecular weight polyethylene (UHMWPE) according to ISO 5834-2, with a small cobalt-chrome pin included as an opaque radiographic marker.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 5 2001

Ms. Irene Gosset
Regulatory Affairs
Tornier S.A.
161, rue Lavoisier
38330 Montbonnot
France

Re: K012212
Trade/Device Name: Aequalis Shoulder System
Regulation Number: 888.3660, 888.3690
Regulatory Class: I
Product Code: KWS, HSD
Dated: July 10, 2001
Received: July 16, 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 Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012212

Device name: ***AEQUALIS Shoulder System***

Indication for use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

D Mitchell for CAM

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

510(k) Number K012212

Prescription use X OR Over-The-Counter Use _____

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