K973453 DEC - 9 1997

Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	***Tornier Cement Restrictor*** Tornier S.A.

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

1. **Device Name:**

   Trade Name: ***Tornier Cement Restrictor***

   Common Name: Canal Plug, Cement Restrictor

   Classification Name: Cement Obturator

2. **Establishment Name & Registration Number:**

   Name: Tornier S.A.

   Number: 8020756

3. **Classification:**

   Cement Obturator, 21 CFR, §878.3300

   § 878.3300 Surgical mesh. (a) Identification. Surgical mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists. Examples of surgical mesh are metallic and polymeric mesh for hernia repair, and acetabular and cement restrictor mesh used during orthopedic surgery. (b) Classification. Class II.

   Device Class: Class II

   Classification Panel: Orthopaedic

   Product Code: 87LZN

4. **Special Controls:**

   Not applicable to this device.

5. **Labeling:**

   IMPORTANT: The implantation of a joint prosthesis requires a knowledge of anatomy, biomechanics and reconstructive surgery of the locomotive apparatus and may be performed only by a qualified surgeon. The surgeon must operate in accordance with current information on the state of scientific progress and the art of surgery.

   Federal (United States) Law restricts this device to sale, distribution and use by or on the order of a physician only.

   Warnings and cautions: Never re-use an implant, even if it is in perfect condition. Never resterilize an implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 1997

Mr. David W. Schlerf
Buckman Company, Inc.
Representing Tornier S.A.
1000 Burnett Avenue, Suite 450
Concord, California 94520

Re: K973453
Tornier Cement Restrictor
Regulatory Class: II
Product Codes: JDI and FTM
Dated: August 20, 1997
Received: September 11, 1997

Dear Mr. Schlerf:

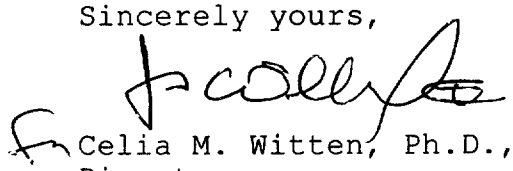
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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" (21 CFR 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/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K973453

Device Name: *Tornier Cement Restrictor*

Indications For Use:

1. **Total Shoulder Arthroplasty**
2. **Total Hip Arthroplasty**
3. **Intramedullary Occlusion**
4. **Cement Pressurization**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative Devices
510(k) Number K973453

Prescription Use X OR Over-The-Counter Use _____

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