

AUG 31 2000

K994041

Tornier® Radial Head
August 14, 2000

Summary of Safety and Effectiveness Information Premarket Notification, Section 510(k)	Tornier® Bipolar Radial Head Prosthesis K994041
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Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**

Trade Name: Tornier® *Bipolar Radial Head Prosthesis*
Common Name: Radial head prosthesis
Classification Name: Unclassified

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

Name: Tornier S.A.
Number: 8020756

3. **Classification:**

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

(a) Identification. An elbow joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint. This generic type of device includes prostheses that consist of a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a radial resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) Classification. Class II.

§ 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis.

(a) Identification. An elbow joint radial (hemi-elbow) polymer prosthesis is a device intended to be implanted made of medical grade silicone elastomer used to replace the proximal end of the radius.

(b) Classification. Class II.

Device Class: Presumed Class II
Classification Panel: Orthopaedic
Product Code: 87KWI, 87JDB

4. **Special Controls:**

As a Class II medical device, this device is subject to special controls as promulgated by the FDA.

5. **Labeling:**

Federal (United States) Law restricts this device to sale by or on the order of a physician. Please refer to Appendix I for samples of device labeling. Obtain and read all product literature before using the device.

6. **Summary Basis for Equivalence:**

Based on the use of biocompatible materials, intended uses, basic design, clinical performance, biomechanical testing and surgical technique, the **Tornier® Bipolar Radial Head Prosthesis** is substantially equivalent or superior to the above referenced legally marketed devices.

7. **Equivalent / Predicate Device(s):**

Swanson Radial Head Implant, Wright Medical Technologies, Inc.
Swanson Titanium Radial Head Implant, Wright Medical Technologies, Inc.

8. **Device Description:**

The **Tornier® Bipolar Radial Head Prosthesis** developed by **Tornier** combines modern materials, proven design concepts, and established operative techniques to produce an evolutionary advance in radial head implant replacement of the elbow.

Design:

The design of the **Tornier Bipolar Radial Head Prosthesis** is, as the name implies, bipolar in nature. Bipolar implants as typified by many hip and hemi-hip implants possess two separate articulation surfaces. Movement in a bipolar joint can occur between either or both of the bipolar articulating surfaces. The remaining "side" of the natural bony joint may articulate with the head of the implant, the ball of the stem may articulate within the cup of the head of the implant and/or movement between the ball, cup and remaining natural joint surfaces may occur simultaneously. Depending upon the type of movement and the loading conditions imposed, the articulation movement of the affected joint takes place following the path of least resistance. The shaft of the stems are micro-bead blasted to a fine mate finish with the neck and ball of the stem mirror finished. The ultra high molecular weight polyethylene head insert is not "finished" per se, but molded and machined to required tolerances and surface configuration.

Materials:

The materials used to construct the device are known as Iron-cobalt-chrome (FeCrCo) and Ultra High Molecular Weight Polyethylene (UHMWPE). The device is made up of three parts, the stem, the metal head and the polyethylene press-fit insert. The stems are made from FeCrCo steel meeting international standard ISO 5832-7 (Feb94). The metal head is made from FeCrCo steel also meeting ISO 5832-7 (Feb94). The UHMWPE head meets ISO 5834-2 (Nov86).

Instrumentation. Specialized instruments are required to properly implant the **Tornier® Bipolar Radial Head Prosthesis**.

9. **Applicant Name & Address:**

Tornier S.A.
B.P. 11 - rue Doyen Gosse
38330 - Saint Ismier - France
011.334.7661.3500
011.334.7661.3533 - fax

10. **Company Contact:**

Irene Gosset
B.P. 11 - rue Doyen Gosse
38330 - Saint Ismier - France
011.334.7661.3500
011.334.7661.3533 - fax

11. **Submission Correspondent:**

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane
Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

12. Manufacturing Facility:

The Tornier® *Bipolar Radial Head Prosthesis* is manufactured by Tornier, S.A.. The product is distributed by Tornier, Inc. in the United States. Tornier, S.A. is a registered medical device manufacturing facility located in France.

13. Performance Data:

Biomechanical and clinical data establish the equivalence of the design when contrasted with the indicated comparison devices.

14. Sterilization Information:

The implantable product is supplied sterile from the manufacturer. The technique used to achieve sterilization is known as gamma radiation sterilization. A radiation dose of at least 2.5 Mrad is utilized. The device may not be secondarily cleaned or resterilized. Once the product packaging is opened or damaged, the product is no longer considered sterile. Packaging must be inspected on arrival for evidence of shipping damage.

Damaged packaging renders the product unsafe and it should not be used. All shipping damaged product should be returned promptly. Subsequently damaged product packaging requires product replacement. Product for use in the operating room must be opened, handled and placed into use following accepted operating room sterile technique. The Sterility Assurance Level (SAL) of the implants is at least 10^{-6} based on the minimum 25 kGy radiation dose.

The surgical instruments required to properly use the device are supplied clean only and must be sterilized prior to each use. Remove all labels and packaging materials before sterilization. Wash the instruments thoroughly before sterilization. The recommended method is steam autoclave sterilization. The recommended sterilization cycle is based on AAMI guidelines. The cycle is saturated steam at 270° F for 30 minutes.

15. Special Guidance Document Information:

This submission was prepared in accordance with the guidance document detailing the content of a Premarket notification for Orthopaedic devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Mr. David W. Schlerf
Tornier, Inc.
c/o Buckman Company, Inc.
200 Gregory Lane
Suite C-100
Pleasant Hill, California 94523

Re: K994041
Trade Name: Tornier Bipolar Radial Head Prosthesis
Regulatory Class: II
Product Code: KWI and JDB
Dated: February 23, 2000
Received: June 29, 2000

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.

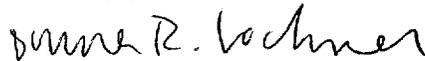
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (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.

Page 2 – Mr. David W. Schlerf

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 at (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: K994041

Device Name: **Tornier® Bipolar Radial Head Prosthesis**

Indications For Use:

- Acute traumatic fracture of the proximal radius not suitable for internal fixation.
- Unstable elbow following radial head resection, including wrist pain following radial head resection after radio-cubital dislocation or impingement of the carpus.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY
Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994041

Prescription Use 2^u
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No
(Optional format 1-2-96)