K041873
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AUG 2 5 2004

TORNIER
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Summary of Safety and Effectiveness information
Special 510(k) – AEQUALIS Reversed Shoulder Prosthesis

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

1) Device name
Trade name: *AEQUALIS Reversed Shoulder Prosthesis*
Common name: Total-Shoulder System and Hemi-Shoulder System
Classification name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

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

3) Company contact
Tornier S.A.
Mrs Mireille Lémery
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ZIRST - 161, rue Lavoisier
38330 Montbonnot - France
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4) Classification
Device class: Class II
Classification panel: Orthopedic
Product code: KWS
§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

5) Equivalent / Predicate device
Aequalis Reversed Shoulder Prosthesis, TORNIER SA, K030941
Aequalis Shoulder System, TORNIER SA, K952928
Bipolar Shoulder Prosthesis, BIOMET Inc, K991585
Delta Shoulder, DePuy Inc, K021478

6) Device description
The *Aequalis Reversed Shoulder Prosthesis* is intended to be used to relieve pain and significant disability following massive and non repairable cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.

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SIRET : 070 501 275 000 13
R.C.S. : B 070 501 275
CODE APE : 331 B

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Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The *Aequalis Reversed Shoulder Prosthesis* is intended to accomplish these goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm.
The *Aequalis Reversed Shoulder Prosthesis* is a semi-constrained system composed of a humeral and a glenoid parts.

The present device modification submission consists in the addition of components to the *Aequalis Reversed Soulder prosthesis* in order to have the possibility to transform the *Aequalis Reversed Soulder Prosthesis* in a standard hémi or total prosthesis in some clinical cases encountered during the surgical procedure.

The present Device Modification submission corresponds to the addition of 3 components to the components of the *Aequalis Reversed Shoulder prosthesis*:
- Hemi-prosthesis adaptor diameter 36 mm,
- Hemi-prosthesis adaptor diameter 42 mm,
- Adaptor metaphysis union screw.

with the same indications for use already covered by the previous 510(k) clearance.

7) Materials
The hemi-prosthesis adaptor and the adaptor methaphysis union screw are made of Chromium Cobalt alloy according to ISO standards 5832-7 or ISO 5832-12.

8) Indications
The Aequalis Reversed Shoulder Prosthesis is indicated for patients, with a functional deltoid muscle, as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear.
The Aequalis Reversed Shoulder Prosthesis humeral component is intended for cemented use only and the glenoid component is intended for non cemented use with 4 screws for fixation.

When during the primary surgery the glenoid stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Reversed prosthesis in to a non reversed hemi-prosthesis.
When, in case of revision of a Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Reversed prosthesis in to an anatomical non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2004

Ms. Mireille Lemery
Regulatory Affairs and Quality Engineer
Tornier S.A.
Zirst -161, rue Lavoisier
38330 Montbonnot, France

Re: K041873
Trade/Device Name: Aequalis Reversed Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: July 9, 2004
Received: July 13, 2004

Dear Ms. Lemery:

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 (301) 594-4659. 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,

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

Indications for Use

510(k) Number (if known): K041873

Device Name: *Aequalis Reversed Shoulder Prosthesis*

Indications For Use:

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When, in case of revision of a Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Reversed prosthesis in to an anatomical non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Prescription Use ✓ (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)

for Mark N Milhous

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

510(k) Number K041873