MAY 1 4 2004

510(k) SUMMARY:

1.0 Device Name:

Trade name: *Aequalis Reversed Shoulder Prosthesis*
Common name: Total shoulder prosthesis
Classification name: Shoulder joint, metal/polymer semi-constrained cemented prosthesis
Device class: Class II
Classification panel: Orthopedic
Product code: 87KWS

2.0 Sponsor:

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3.0 Submitted by / Company contact:

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4.0 Equivalent / Predicate device:

BIPOLAR SHOULDER PROSTHESIS, Biomet (K991585),
Delta 3 Reversed Shoulder Prosthesis, DePuy (K021478)
AEQUALIS Shoulder System, Tornier (K952928)

5.0 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. 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 humeral component:

The humeral part is made of 3 parts consisting of interchangeable stems, metaphysis , and inserts, that may be assembled in different configurations thus accommodating a large variation in patient size and anatomy.

The metaphyseal parts are fixed to the stem by a screwing fixation secured by a polyethylene breaking system. A lateralization spacer can be added to the humeral metaphysis in order to vary the lateralization.

The inserts are impacted on to the conic shape of the metaphysis. A polyethylene peg guides it in the correct position.

The stems are made of cobalt-chrome in 4 diameters The metaphyseal parts are manufactured from cobalt-chrome, in 2 sizes. The inserts are available in polyethylene in 6 sizes. The lateralization spacers are made of cobalt-chrome and are available in 2 sizes.

The glenoid component:

The glenoid part is composed of a base made of titanium alloy, on which is impacted a sphere of chrome cobalt. The assembly is secured by a central and internal screw. The sphere is available in two diameters congruent with the humeral insert.

The metallic base of the glenoid is fixed to the bone by using 4 compression screws for fixation.

6.0 Materials:

The material used in the composition of the *Aequalis Reversed Shoulder Prosthesis* implants is marked on the packaging. Humeral stems are manufactured from Chromium Cobalt alloy (CoCr) according to ISO standard 5832-7 or ISO 5832-12. Humeral metaphysis components are made of Chromium Cobalt alloy (CoCr) according to ISO standard 5832-4. Metaphyseal inserts are made of ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2. The lateralization spacers are made of Chromium Cobalt alloy according to ISO standards 5832-7 and 5832-12. The base of the glenoid implant is manufactured from Titanium alloy according to ISO standard 5832-3 and the anchoring screws are manufactured from Titanium alloy according to ISO standard 5832-3. The glenoid sphere from Chromium Cobalt alloy (CoCr) according to ISO standards 5832-7 or 5832-12 and the associated securing mechanism is made of Chromium Cobalt according to ISO standards 5832-7 or 5832-12 and Titanium alloy according to ISO standard 5832-3.

7.0 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.

8.0 Standards / Testing:

All components and parts are biocompatible and comply with the appropriate standards and performance testing for safety and effectiveness in accordance with:

1. ISO 5834-2:1998: Implants for Surgery-Ultra-high Molecular Weight Polyethylene-Part 2: Moulded Forms;
2. ISO standard 5832-3: Implants for Surgery-Metallic Materials - Titanium alloy - Part 3; Titanium alloy;
3. ISO 5832-4:1996: Implants for Surgery-Metallic Materials- Part 4: Cobalt-Chromium-Molybdenum Casting Alloy;
4. ISO 5832-7:1996: Implants for Surgery-Metallic Materials- Part 7: Cobalt-Chromium-Molybdenum Casting Alloy;
5. ISO 5832-12:1996: Implants for Surgery-Metallic Materials- Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy; and,
6. American Society for Testing and Materials: F 1378-97 Standard Specification for Shoulder Prosthesis.

Sterilization is accomplished by gamma radiation and the process has been validated and complies with all appropriate standards including ISO 10993

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2004

TORNIER S.A.
C/o Mr. Donald F. Grabarz
Managing Director
International Regulatory Consultants, L.C.
Mid Valley Professional Plaza
7651 S. 700 West, Suite 105
Salt Lake City, Utah 84047

Re: K030941
Trade 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: March 15, 2004
Received: March 17, 2004

Dear Mr. Grabarz:

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,

for

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

SUMMARY STATEMENT

510(k) Number: K030941

Device Name: **Aequalis Reversed Shoulder Prosthesis**

Indications 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)

Prescription use X or Over-the-Counter Use _____

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

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

510(k) Number K030941