TORNIER

K062661

DEC 22 2006

Summary of Safety and Effectiveness information
510(k) Premarket Notification – Aequalis Resurfacing Head

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

1) Device name

Trade name:	**Aequalis Resurfacing Head**
Common name:	Humeral Resurfacing
Classification name:	888.3690 Shoulder joint, humeral (hemi-shoulder), metallic uncemented prosthesis

2) Submitter

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

3) Company contact

Tornier
Mrs Mireille Lémery
Regulatory affairs Manager
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
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e-mail : mireille.lemery@tornier.fr

4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	HSD

5) Equivalent / Predicate device

Aequalis Shoulder System, Tornier, K952928, K012212, K041339, K043077, K060209
Aequalis Shoulder Fracture System, Tornier, K994392, K003728, K032679, K043077, K060209
Copeland MB/HA Resurfacing Humeral Head, Biomet, Inc, K010827
Global CAP resurfacing Replacement Shoulder, DePuy Orthopaedics, Inc, K033516

6) Device description

The Aequalis Resurfacing Head is a humeral head resurfacing device. It requires less bone and cartilage removal, which makes it much more conservative than total joint implants. Revision or arthrodesis can be undertaken easily because the bone stock has been maintained with no loss of length. The main advantages of humeral head resurfacing are preservation of bone and the relatively simple surgical technique.

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With the Aequalis Resurfacing Head the natural glenoid elements of the shoulder may be conserved or replaced as warranted by the state of disease or injury.

7) Materials

The resurfacing head is manufactured from Cobalt-Chromium alloy according to ISO 5832-4. The bone contacting surfaces are coated with titanium plasma spray according to ASTM F1580 and hydroxylapatite according to ASTM F1185.

8) Indications

The Aequalis Resurfacing Head is indicated as a total or hemi shoulder joint replacement where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable.
The replacement of the joint with this device is indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: osteoarthritis, rheumatoid arthritis, post-traumatic arthritis. Primary and secondary necrosis of the humeral head.
- Humeral head fracture.

The Aequalis Resurfacing Head is intended for uncemented use only.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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TORNIER S.A.S
% Ms. Mireille Lemery
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38334 Saint – Ismier Cedex
France

DEC 2 2 2006

Re: K062661
Trade/Device Name: Aequalis Resurfacing Head
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi shoulder), metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: November 30, 2006
Received: December 04, 2006

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.

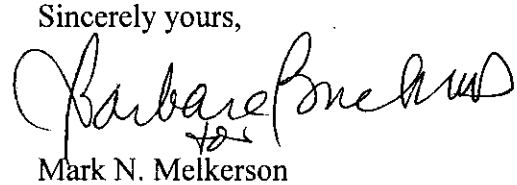
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
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): K062261

Device Name: Aequalis Resurfacing Head

Indications For Use:

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The replacement of the joint with this device is indicated to relieve severe pain or significant disability caused by:

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- Humeral head fracture.

The Aequalis Resurfacing Head is intended for uncemented use only.

Prescription Use X (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)

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

510(k) Number K062661