K081707

p. 1/2

TORNIER

JUL 17 2008

510(k) Summary

510(k) SPONSOR: Tornier
100 Capital Drive, Suite 201,
Warsaw, IN 46582

CONTACT PERSON: Jeff Ondrla,
Vice President, Product Development
(574) 527-9951
JOndrla@Tornier.com

TRADE NAME: Aequalis Shoulder Fracture System and Aequalis Shoulder System

COMMON NAMES: Total shoulder prosthesis

CLASSIFICATION, and CLASS: 21 CFR 888.3660 - Shoulder joint metal/polymer semi-constrained cemented prosthesis; Class II

PRODUCT CODES: 87 KWS

PREDICATE DEVICES:

Aequalis Shoulder Fracture System: K994392, K003728, K012212, K032679 and K060209

Aequalis Shoulder System: K952928, K980244, K012212, K041339, K043077 and K060209

DVO (now Tornier) Total and Hemi Shoulder System: K060988

DEVICE DESCRIPTION:
The labeling for the Aequalis Shoulder Fracture System and Aequalis Shoulder System is being modified to indicate that, when used as total shoulder prostheses, the Aequalis Shoulder Fracture System humeral stems, Aequalis Shoulder System humeral stems and Aequalis humeral heads are compatible with the Affiniti pegged glenoid components in addition to the Aequalis glenoid components that have been previously cleared for use with these systems.

The Affiniti pegged glenoid components are available in sizes 40 - 56.

K081707 p 2/2

INDICATIONS FOR USE:

Aequalis Shoulder System (excluding Aequalis Shoulder Fracture System):

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies : arthrosis, rheumatoid arthritis, post-traumatic arthrosis.
- Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revision surgery when other treatments or devices have failed.

Aequalis Shoulder Fracture System

- Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including
    - humeral head fracture and displaced 3-or 4-part proximal humeral fractures.
    - Revision surgery when other treatments or devices have failed.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

The indications, intended uses, designs, materials and manufacturing methods for the Aequalis Shoulder Fracture System and Aequalis Shoulder System have not changed from those cleared previously in K060209. These systems, with labeling modified to include compatibility with the Affiniti pegged glenoid components, are therefore substantially equivalent to the systems that have been cleared previously.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tornier
% Mr. Jeff Ondrla
Vice President, Product Development
100 Capital Drive, Suite 201
Warsaw, IN 46582

JUL 17 2008

Re: K081707
Trade/Device Name: Aequalis Shoulder Fracture System and Aequalis Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: June 13, 2008
Received: June 17, 2008

Dear Mr. Ondrla:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems ~~at (240) 276-3464. You may obtain other general information on your responsibilities under the~~ Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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

K081707

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Aequalis Shoulder Fracture System and Aequalis Shoulder System

Aequalis Shoulder System (excluding Aequalis Shoulder Fracture System):

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies : arthrosis, rheumatoid arthritis, post-traumatic arthrosis.
- Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revision surgery when other treatments or devices have failed.

Aequalis Shoulder Fracture System

- Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including
    - humeral head fracture and displaced 3-or 4-part proximal humeral fractures.
    - Revision surgery when other treatments or devices have failed.

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)

Barbara Buchell

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

510(k) Number K081707