TORNIER

510(k) Summary

JAN 27 2009

510(k) SPONSOR and APPLICANT:	**Tornier** 100 Capital Drive Suite 201 Warsaw IN 46582
CONTACT PERSON:	Brian Hodorek Sr. Development Engineer (574) 268-0861 x 344 BHodorek@Tornier.com
TRADE NAME:	Aequalis Humeral Nail System
COMMON NAMES:	Intramedullary Nail
CLASSIFICATION and CLASS:	21 CFR 888.3020 - Intramedullary Fixation Rod, Class II
PRODUCT CODE:	87 HSB – Intramedullary Fixation Rod and Accessories
PREDICATE DEVICES:	• Howmedica Osteonics T2 Proximal Humeral Nail (K042396) • FH Industrie Titanium Telegraph Humeral Nail (K042332) • Smith & Nephew TriGen Straight Humeral Nail System (K032722)

DEVICE DESCRIPTION:

The Aequalis Humeral Nail System includes intramedullary nails and screws. The Aequalis Humeral Nail is a straight, cannulated intramedullary nail with a 9mm proximal diameter and a distal diameter that tapers from 8mm to 5mm. It is 130mm long and is available in right and left configurations. The proximal end of the nail contains screw holes in four axes for proximal locking using 5mm cannulated screws. The proximal end of the nail also contains a cannulated polyethylene insert with screw holes aligned with those of the nail. This insert is intended to help prevent the proximal screws from backing out. The distal end of the nail incorporates one slot and one screw hole for distal locking using 4.5mm screws. The nail and screws are manufactured from anodized Ti-6Al-4V alloy.

INDICATIONS:

The Aequalis Humeral Nail System is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact calotte, or Humeral Fractures according to Neer-Classification (2, 3 and 4 part fractures).

COMPARISON TO PREDICATES:

The Aequalis Humeral Nail System is substantially equivalent to the predicate devices based on similarities in indications for use, design and materials and the results of stress calculations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2009

Tornier
% Mr. Brian Hodorek
100 Capital Drive
Suite 201
Warsaw, IN 46582

Re: K082754
Trade/Device Name: Aequalis Humeral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: II
Product Code: HSB
Dated: January 19, 2009
Received: January 21, 2009

Dear Mr. Hodorek:

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

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): K082754 (pg 1/1)

Device Name: Aequalis Humeral Nail System

Indications for Use:

The Aequalis Humeral Nail System is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact calotte, or Humeral Fractures according to Neer-Classification (2, 3 and 4 part fractures).

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 K082754