K023067
page 1 of 1

510(k) Summary for the T2 Supracondylar Nail System

DEC 11 2002

Proprietary Name:	T2 Supracondylar Nail System
Common Name:	Intramedullary Nail
Classification Name and Reference	Intramedullary Fixation Rod 21 CFR §888.3020
Regulatory Class:	Class II
Device Product Code:	87 HSB
For Information contact:	Karen Ariemma, Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 831-5718 Fax: (201) 831-6038
Date Summary Prepared:	September 26, 2002

Description:
The T2 Supracondylar Nails are retrograde nails with a one-piece round profiled shaft design. The nails are cannulated and have a closed-section design with proximal rounded end. The T2 Supracondylar Nail is available in two versions: Short and Long. The T2 Supracondylar is available in lengths from 170 mm to 440 mm and in diameters from 9 mm to 14 mm.

Intended Use:
The subject T2 Supracondylar Nail System is an internal fixation system comprised of intramedullary nails and the related locking screws, condyle screws, a condyle screw nut and an end cap. The subject device is intended to provide strong and stable internal fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

Substantial Equivalence:
The design and function of the T2 Supracondylar Nail is substantially equivalent to that of the predicate device. Both the subject and predicate systems offer nails in varying lengths, and offer a combination of locking screws, condyle screws, a condyle screw nut and an end cap.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2002

Ms. Karen Ariemma
Regulatory Affairs Specialist
Quality Assurance, Regulatory Affairs and Clinical Research
Stryker Howmedica Osteonics Corp.
59 Route 17 South
Allendale, New Jersey 07401

Re: K023267
Trade Name: T2 Supracondylar Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: September 17 ,2002
Received: September 30, 2002

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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.

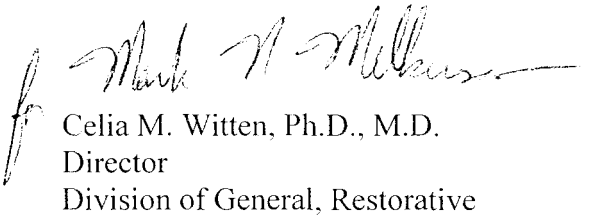
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known): K023267

Device Name: T2 Supracondylar Nail System

Indications For Use:

Intended Use

The T2 Supracondylar Nail System is intended to provide strong and stable internal fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

Indications for Use

The subject device is indicated for femoral fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Supracondylar fractures, including those with intra-articular extension
- Ipsilateral femur fractures
- Fractures distal to a hip joint
- Nonunions and malunions
- Reconstruction

Mark N Mellema

(Division Sign-Off)
Division of Cardiovascular, Interventional
and Neurological Devices
510(k) Number K023267 12-11-02 MNM

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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