Femoral Trochanteric Nail (FTN) System
510(k) SUMMARY
September 2004

K042440

I. **Company**: Alphatec Manufacturing, Inc.
6110 Corte Del Cedro
Carlsbad, CA 92009, USA
(760) 431-9286

OCT 7 - 2004

II. **Contact Person**: Ellen Yarnall, Director of Regulatory Affairs

III. **Trade/Proprietary Name**: Femoral Trochanteric Nail (FTN) System

IV. **Product Description**:

The Femoral Trochanteric Nail (FTN) System consists of an intramedullary nail, lag screw, cap screw, optional anti-rotation pin, and distal static or dynamic screws. The proximal diameter is 16 mm with distal diameters offered in diameters of 10, 12, or 14 mm. The proximal portion of the nail has two holes, one for a lag screw and one for an anti-rotational pin. The proximal holes are angled at 125°, 130° or 135°. All implants are manufactured from titanium alloy (Ti-6Al-4V ELI).

V. **Intended Use**:

The Femoral Trochanteric Nail (FTN) System is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures.

VI. **Substantial Equivalence**:

The FTN System is substantially equivalent to the following predicate devices:

Trade/Proprietary Name	Manufacturer	Clearance
Trochanteric Nail	Depuy Orthopedics	K010780
Trochanteric Nail	AOS	K021008
Trochanteric Dyax™ Nail System	Howmedica Osteonics	K013524

VI. **Performance Data**:

Mechanical and dynamic testing of the Alphatec FTN System was performed. The test results demonstrated that the mechanical performance of the Alphatec FTN is at least comparable to, if not better than those of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Ms. Ellen A. Yarnall
Director of Regulatory Affairs
Alphatec Manufacturing, Inc.
6110 Corte Del Cedro
Carlsbad, California 92009

Re: K042440
Trade/Device Name: Femoral Trochanteric Nail (FTN) System
Regulation Number: 21CFR 888. 3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: September 8, 2004
Received: September 9, 2004

Dear Ms. Yarnall:

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.

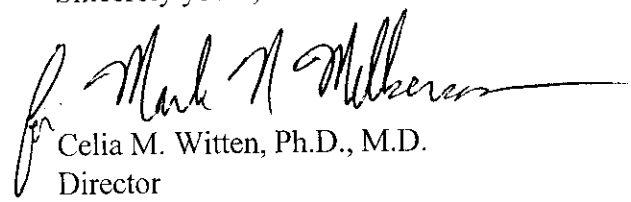
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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

INDICATIONS FOR USE

510(k) Number (if known): K042440

Device Name: Femoral Trochanteric Nail (FTN) System

Indications for Use:

The Alphatec Femoral Trochanteric Nail (FTN) System is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these 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 K042440