

SEP 22 1999



Premarket Notification
Pylon Intramedullary Nail System
Alphatec Manufacturing, Inc.

1 of 2

510(k) Summary

510(k) Number K992350

Manufacturer Identification

Submitted By: Alphatec Manufacturing, Inc.
42-160 State Street
Palm Desert, CA 92211
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Contact Person: Jason Blain
Manager of Product Development

Date Summary Prepared: July 12, 1999

Device Identification

Proprietary Name: Pylon Intramedullary Nail System

Common Name: Intramedullary Fixation System

Classification: 21 CFR 888.3020: Rod, Fixation, Intramedullary and Accessories

Device Description

The Pylon Intramedullary Nail System consists of intramedullary rods and screws for fixation inside the canal of the tibia or femur. The rods are cylindrically shaped and either made of a solid or cannulated construct, depending on the outer diameter of the rod. Rods are available in a variety of diameters and lengths and have holes located in the proximal and distal ends for fixation to bone by means of bone screws. Bone screws are also available in a multitude of diameters and lengths. An end cap is available that screws into the proximal end of the nails to prevent bone ingrowth which may hamper the attachment of extraction instrumentation.

All components of the Pylon Intramedullary Nail System are manufactured from titanium alloy (Ti-6Al-4V).

Intended Use of the Device

The Pylon Intramedullary Nail System is indicated for internal fixation of tibial or femoral fractures including low subtrochanteric fractures, transverse fractures, oblique and spiral fractures, segmental fractures, comminuted fractures, high supracondylar fractures, fractures with bone loss, stabilization for bone transport or lengthening and



shortening, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the bone shaft, nonunions, malunions, metaphyseal/diaphyseal junction fractures, and acute bone lengthening and shortening.

Substantial Equivalence

The Pylon Intramedullary Nail System is substantially equivalent to ACE AIM Titanium Nails (Depuy ACE, a Johnson and Johnson company). The Pylon Intramedullary Nail System is similar to the listed predicate device in design, function, materials used, and indications for use.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jason Blain
Manager of Product Development
Alphatec Manufacturing, Inc.
42-160 State Street
Palm Desert, California 92211

Re: K992350
Trade Name: Pylon Intramedullary Nail System
Regulatory Class: II
Product Code: HSB
Dated: July 12, 1999
Received: July 14, 1999

Dear Mr. Blain:

We have reviewed your Section 510(k) 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Pre-market Approval), 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 895.

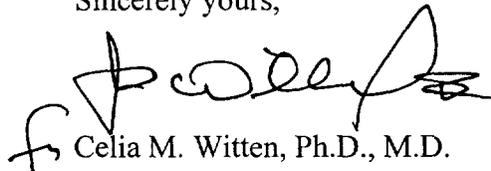
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820), and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Jason Blain

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is stylized and includes a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Intended Uses/Indications

510(k) Number: K992350

Device Name: Pylon Intramedullary Nail System

Indications for Use:

The Pylon Intramedullary Nail System is indicated for internal fixation of tibial or femoral fractures including low subtrochanteric fractures, transverse fractures, oblique and spiral fractures, segmental fractures, comminuted fractures, high supracondylar fractures, fractures with bone loss, stabilization for bone transport or lengthening and shortening, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the bone shaft, nonunions, malunions, metaphyseal/diaphyseal junction fractures, and acute bone lengthening and shortening.

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K992350

Prescription Use _____
(Per 21 CFR 801.109)