JAN - 3 2000

510(k) Summary

510(k) Number K993873

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: November 12, 1999

Device Identification

Proprietary Name: Alphatec External Fixation System Compression/Distraction Rod

Common Name: External Fixation System

Classification: 21 CFR 888.3030: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

Device Description

The Alphatec External Fixation System Compression/Distraction (CD) Rod consists of a CD rod that is available in two lengths and a CD rod to rod connector. These components are designed to be used in conjunction with the Alphatec External Fixation System and the Alphatec Wire External Fixation System which were the subject of prior premarket notifications. The additional use of the CD rod with the systems listed adds the capabilities of limb lengthening during fracture fixation.

The CD rod and CD rod to rod connector are manufactured from titanium alloy (Ti-6Al-4V).

Intended Use of the Device

The complete Alphatec External Fixation System is indicated for limb salvage from traumatic injury; fracture treatment (i.e., long bone fracture, including the tibia, femur, humerus, radius, and ulnar bones); reconstruction of extremities with deformity and dysfunction; limb lengthening; arthrodesis; and pelvic fractures.

Substantial Equivalence

The Alphatec External Fixation System with the addition of the CD rod is substantially equivalent to the Howmedica Hoffmann II External Fixation System, Ace Unifix External Fixation System, and the Smith & Nephew Ilizarov External Fixator. The Alphatec External Fixation System is similar to each of the listed predicate devices in one or more of the following areas: design, function, materials used, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2000

Mr. Jason Blain
Manager of Product Development
Alphatec Manufacturing, Inc.
42-160 State Street
Palm Desert, California 92211-5148

Re: K993873
Trade Name: Alphatec External Fixation System Compression/Distraction Rod
Regulatory Class: II
Product Code: KTT
Dated: November 12, 1999
Received: November 15, 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 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 (Premarket 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.

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) 594-4595. 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,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Uses/Indications

510(k) Number: K993873

Device Name: Alphatec External Fixation System

Indications for Use:

The Alphatec External Fixation System is indicated for limb salvage from traumatic injury; fracture treatment (i.e., long bone fracture, including the tibia, femur, humerus, radius, and ulnar bones); reconstruction of extremities with deformity and dysfunction; limb lengthening; arthrodesis; and pelvic fractures.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993873