APR 2 6 2000

510(k) Summary

510(k) Number K993513

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: January 24, 2000

Device Identification

Proprietary Name: Deltaloc Anterior Cervical Plate System

Common Name: Spinal Intervertebral Body Fixation Orthosis

Classification: 21 CFR 888.3060: Appliance, Fixation, Spinal, Intervertebral Body

Device Description

The Deltaloc Anterior Cervical Plate System consists of plates and screws that are used for attachment to the anterior cervical spine. Plates are offered in a variety of sizes with varying numbers of screw holes to accommodate single to quadruple level fusions. Plates are shaped with both radial and lordotic curvature and contain a deformable tab at each screw hole to capture the screws to the plate, preventing screw digression. Screws are offered in two diameters and four lengths per diameter. All screws are also available so that their angle relative to the plate is fixed or variable.

The plates of the Deltaloc Anterior Cervical Plate System are manufactured from commercially pure titanium and the screws are manufactured from titanium alloy (Ti-6Al-4V).

Intended Use of the Device

The Deltaloc Anterior Cervical Plate System is indicated for: use in the anterior cervical spine (C2-C7); patients with trauma (including fractures), spondylolisthesis, degenerative spondylosis, degenerative disc disease (defined as back pain of discogenic origin with

degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, and tumors.

Substantial Equivalence

The Deltaloc Anterior Cervical Plate System is substantially equivalent to the Synthes CSLP (Cervical Spine Locking Plate) System. The Deltaloc Anterior Cervical Plate System is similar to the listed predicate device in 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

APR 2 6 2000

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

Re: K993513
Trade Name: Deltaloc Anterior Cervical Plate System
Regulatory Class: II
Product Code: KWQ
Dated: January 24, 2000
Received: January 27, 2000

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 (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) 594-4659. 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/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

Intended Uses/Indications

510(k) Number: K993513

Device Name: Detaloc Anterior Cervical Plate System

Indications for Use:

The Deltaloc Anterior Cervical Plate System is indicated for use in the anterior cervical spine (C2-C7); patients with trauma (including fractures), spondylolisthesis, degenerative spondylosis, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, and tumors.

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993513