IX. 510(k) Summary

APR - 2 2004

SUBMITTER: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02780

CONTACT PERSON: Lisa A. Gilman

DATE PREPARED: January 22, 2004

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis

PROPRIETARY NAME: Eagle Anterior Cervical Plate System

PREDICATE DEVICES: Peak Polyaxial Anterior Cervical Plate System (K971730)

DEVICE DESCRIPTION: The Eagle Anterior Cervical Plate System consists of an assortment of plates and screws.

The Eagle Anterior Cervical Plate System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

INTENDED USE: The indications for use for the modified devices described in this submission are the same as those for the previously cleared Peak Polyaxial Anterior Cervical Plate System (K971730). The indications are as follows:

The Eagle Anterior Cervical Plate System is intended for anterior cervical intervertebral body fixation. These systems are indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indications include symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc

	confirmed by history and radiographic studies), re-operation for failed fusion, or instability following surgery for the above indications.
MATERIALS:	Manufactured from ASTM F-136 implant grade titanium alloy.
PERFORMANCE DATA:	Performance data were submitted to characterize the Eagle Anterior Cervical Plate System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

Ms. Lisa Gilman
Regulatory Affairs Associate
Depuy Spine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K040197
Trade Name: Eagle Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 10, 2004
Received: March 12, 2004

Dear Ms. Gilman:

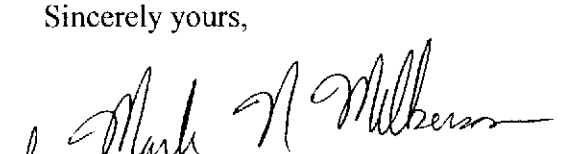
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4659. 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

III. Indications for Use

510(k) Number (if known): K040197

Device Name: Eagle Anterior Cervical Plate System

Indications For Use:

The Eagle Anterior Cervical Plate System is intended for anterior cervical intervertebral body fixation. These systems are indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indications include symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), re-operation for failed fusion, or instability following surgery for the above indications.

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040197

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)