Section 5 – 510(k) Summary – K082504

JAN 27 2009

General Information

Owner's Name:	Apollo Spine
Address:	307 Placentia Ave, Suite 111 Newport Beach CA 92663
Telephone Number:	(949) 645-7746
Fax Number:	(949) 645-7749
Contact Person:	Kamran Aflatoon
Subject Device Name:	Comet Anterior Cervical Plate System
Trade Name:	Comet Anterior Cervical Plate System
Common/Usual Name:	Anterior Cervical Plate System
Classification Name:	KWQ – Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3060; Class II
Predicate Device Name:	Synthes Anterior Cervical Plate System
Trade Name:	Synthes Anterior Cervical Plate System
Common/Usual Name:	Anterior Cervical Plate System
Classification Name:	KWQ – Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3060; Class II
Premarket Notification:	K926453, SE date Oct. 12, 1993

Device Description
The Comet Anterior Cervical Plate System consists of an anterior cervical plate offered in lengths ranging from 10mm through 22mm. Four (4) barbed plate fixation pins are permanently affixed to the plate. A set of two (2) plate fixation screws are used to secure the plate to the superior and inferior vertebrae. Plate fixation screws are offered in two (2) diameters, each in 14mm, 16mm and 18mm lengths.

Indications for Use
The Comet Anterior Cervical Plate System is indicated for anterior cervical fixation for the following indications: degenerative disc disease, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Performance Testing
Performance data demonstrated that the Comet Anterior Cervical Plate System is substantially equivalent to the predicate device and/or met pre-determined acceptance criteria. The risks associated with use of the new device were found acceptable when evaluated by FMEA.

Bench tests performed in accordance with FDA's May 2004 *Guidance for Industry and Staff Spinal System 510(k)s* and ASTM F1717-04 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model* included assessments of static and dynamic axial compression bending and static torsion.

No biocompatibility testing was conducted; all materials used in the manufacture of the Comet Anterior Cervical Plate System device have been previously cleared for similar devices.

Conclusion
The Comet Anterior Cervical Plate System meets all the pre-determined acceptance criteria of the testing performed to confirm safety and effectiveness; the Comet Anterior Cervical Plate System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Apollo Spine, Inc.
% Ms. Pamela Papineau, RAC
Delphi Medical Device Consulting
5 Whitcomb Ave
Ayer, Massachusetts 01432

JAN 27 2009

Re: K082504
Trade Name: Comet Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Names: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 11, 2008
Received: December 12, 2008

Dear Ms. Papineau:

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.

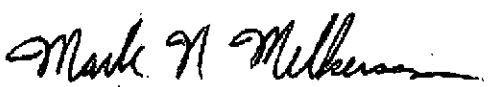
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510(k) Number (if known): K082504

Device Name: Comet Anterior Cervical Plate System

Indications for Use:

The Comet Anterior Cervical Plate System is indicated for anterior cervical fixation for the following indications: degenerative disc disease, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801 Subpart D) (Per 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)

Mark A. Milhous

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

510(k) Number K082504