FEB 16 2012

SPECIAL 510(K) SUMMARY

Submitter Information

Submitter's Name:	Apollo Spine
Address:	3700 Campus Dr. Suite 105 Newport Beach, CA 92660
Telephone:	949-645-1615
Fax:	949-757-0474
Contact Person:	Michele Lucey
Telephone :	603-748-1374

Date Prepared: 15 Feb 2012

Device Trade Name: Eclipse Vertebral Spacer-Cervical

Common/Usual Name: Spinal Intervertebral body fixation orthosis

Classification: 21 CFR §888.3080, 888.3060

Class: II

Product Code: ODP

Intended Use:
When used as an Intervertebral Body Fusion System:

The Eclipse-C Vertebral Spacer System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2 to T1. DDD is defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have completed six weeks of non-operative treatment. The Eclipse-C Vertebral Spacer System implants are to be used with autogenous bone graft. Supplemental fixation is required.

Device Description:
The Eclipse Vertebral Spacer-Cervical acts as a spacer to maintain proper Intervertebral and vertebral body spacing and angulation. The Eclipse Vertebral Spacer is manufactured from PEEK, unalloyed titanium, and Ti6Al4V titanium alloy.

The purpose of this submission is to add an additional footprint in the same heights and lordotic angles as the predicate device.

Comparison to Predicate Device(s):
The indication for use and material composition of The Eclipse Vertebral Spacer-Cervical are the same as the currently cleared predicate device, The Eclipse Vertebral Spacer System (K101588). The only difference is the addition of a foot print size with a resulting increase in the graft chamber area:

Predicate Eclipse Vertebral-Spacer (K101588)	The Eclipse Vertebral- Spacer (Subject Device)
11 x 14 mm depth x width	11 x 14 mm depth x width 14 x 16 mm depth x width (new)

The dimensional differences between the subject device and the predicate are not considered significant because the new size does introduce a new worst case condition (e.g. introduction of a new region with decreased cross sectional area compared to the predicate) and therefore does not raise new questions regarding safety and effectiveness of the device.

Performance Standards:
In consideration of design control activities including risk analysis the non-clinical performance testing performed on the Eclipse Vertebral Spacer Cervical (K101588) including static compression, static torsion, subsidence, and expulsion are applicable in the characterization of the new size because the new size does not introduce a new worst case condition (e.g. introduction of a new region with decreased cross sectional area compared to the predicate), therefore additional mechanical testing on the new size is not warranted.

Performance and SE Determination:
Based on the supporting documentation within this premarket notification, the subject device demonstrates substantial equivalence to the listed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Apollo Spine
% Lakeshore Medical Device Consulting, LLC
Ms. Michele Lucey
128 Blye Hill Landing
Newbury, New Hampshire 03255

FEB 16 2012

Re: K120143
Trade/Device Name: Eclipse Vertebral Spacer System – Cervical
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP
Dated: January 17, 2012
Received: January 18, 2012

Dear Ms. Lucey:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use Statement

510(k) Number: K120143

Device Name: Eclipse Vertebral Spacer System - Cervical

Indications for Use:

The Eclipse-C Vertebral Spacer Sy stem is indicated for in tervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) o f the cervical spine with accompanying radicular symptoms at one disc level fro m C2 to T1. DDD is d efined as pain of discogenic origin with degene ration of the dis c confirmed by history and radiographic studies. These pa tients should have com pleted six weeks of non-operative treatment. The Eclips e-C Vertebral Spacer System implants are to be used with autogenous bone graft. Supplemental fixation is required.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120143