510(k) Summary
Sapphire™ Anterior Cervical Plate System

510(k) Number K101848

OCT 14 2010

Manufacturer Identification

Submitted by:
Spinal Elements, Inc.
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Contact Information:
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Date Prepared: June 29, 2010

Device Indentification

Proprietary Name	Sapphire™ Anterior Cervical Plate System
Common Name	Anterior Cervical Plate System
Device Classification	21 CFR 888.3060 (Appliance, Fixation Spinal Intervertebral Body)
Proposed Regulatory Class	Class II
Device Product Code	KWQ

Purpose of this 510(k)
This 510(k) seeks clearance for a new spinal system.

Device Description
The Sapphire Anterior Cervical Plate System is comprised of plates and screws that are used for attachment to the anterior cervical spine. Both plates and screws are available in a variety of sizes to suit the individual pathology and anatomic condition of the patient. Plates are pre-shaped with radial and lordotic curvature and have large windows for graft and end plate visualization. Plates range in length to accommodate one to four levels of fusion.

Screws are available in both fixed and variable angle designs. Fixed angle screws have a predetermined trajectory relative to the plate. Variable angle screws provide freedom in trajectory of the screws into the vertebral body. All screws are equipped with an internal locking mechanism.

Plates and screws are manufactured from titanium alloy (Ti-6A1-4V) conforming to ASTM F 136 or ISO 5832-3, with certain subcomponents manufactured from nitinol conforming to ASTM F 2063.

Intended Use of the Device

The Sapphire Anterior Cervical Plate System is intended for anterior cervical fixation (C2 – C7) in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (including fracture or dislocation), spinal stenosis, deformities or curvatures (kyphosis, lordosis or scoliosis), tumor, pseudoarthrosis, and failed previous fusion.

Substantial Equivalence

The Sapphire™ Anterior Cervical Plate System was shown to be substantially equivalent previously cleared devices in indications for use, design, function, and materials used.

- Atomic® Anterior Cervical Plate System (K060491).
- Synthes Anterior Cervical Vertebrae Plate (K926453).
- Amendia, LLC. Diamond Anterior Cervical Plate System (K100265).
- Medtronic, Orion Anterior Cervical Plate System (K042499).

Performance Data

Mechanical testing was conducted in accordance with ASTM F 1717, and included:

- Dynamic compression
- Static compression
- Static tension and
- Static torsion.

Mechanical testing indicates that the Sapphire™ Anterior Cervical Plate System is capable of performing in accordance with its intended use and is substantially equivalent to predicate devices.

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

OCT 14 2010

Spinal Elements, Inc.
% Mr. Benjamin A. Kimball
Regulatory Affairs Manager
2744 Loker Avenue West, Suite 100
Carlsbad, California 92010

Re: K101848
Trade/Device Name: Sapphire™ 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: August 18, 2010
Received: September 20, 2010

Dear Mr. Kimball:

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

510(k) Number (if known): K101848

Device Name: Sapphire™ Anterior Cervical Plate System

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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

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