Special 510(k) Summary

Contact Details

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Date Prepared: January 24, 2012

Device Name

Trade Name: Cardiff™
Common Name: Anterior Cervical Plate System
Classification Name: Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060, Product Code: KWQ, Class II) (Orthopedic Review Committee)

Legally Marketed Predicate Device

Previously cleared Cardiff™ Anterior Cervical Plate System 510(k) (K083338)
Previously cleared Sonoma™ Anterior Cervical Plate System 510(k) (K032368)

Device Description

The Cardiff™ Anterior Cervical Plate (ACP) System is intended for anterior interbody screw fixation of the cervical spine only. The Cardiff™ ACP System components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The Cardiff™ ACP System consists of a variety of shapes and sizes of bone plates, screws, and associated instruments. Cardiff™ ACP System implants are manufactured from Titanium and Nitinol alloys. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.

Intended Use

This system is indicated for use in the temporary stabilization of the anterior spine from C2 to C7 during the development of cervical spinal fusions in patients with:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
- trauma (including fracture or dislocation);

- spinal stenosis;
- cervical myelopathy;
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- tumor;
- pseudoarthrosis; and/or
- failed previous fusion

Substantial Equivalence Comparison

This special 510(k) for Cardiff™ is a product line modification of the current Cardiff™ ACP System, which is substantially equivalent to the currently marketed system. The Cardiff™ ACP System implants are manufactured from Titanium 6Al-4V ELI per ASTM F136 and Superelastic Nitinol per ASTM F2063. System modifications include revisions to the component manufacturing process and addition of implant variations. These devices have substantially equivalent technological characteristics as the predicate devices and do not alter the fundamental scientific technology of the previously cleared system.

Category	Previously Submitted Cardiff™ ACP System	Modified Cardiff™ ACP System	Sonoma™ ACP System
Intended Use/ Indications for Use	• Spinal Intervertebral Body Fixation Orthosis	• Spinal Intervertebral Body Fixation Orthosis	Spinal Intervertebral Body Fixation Orthosis
Design	• Graft windows • Screw holes for vertebral fixation • Variety of levels and lengths	• Graft windows • Screw holes for vertebral fixation • Variety of levels and lengths	Graft windows • Screw holes for vertebral fixation • Variety of levels and lengths
Materials	• Titanium and Nitinol Alloy • Instruments of stainless steel, Pomalux or Tecaform	• Titanium and Nitinol Alloy • Instruments of stainless steel, Pomalux or Tecaform	• Titanium and Nitinol Alloy • Instruments of stainless steel, Pomalux or Tecaform
Operating Principle	• Anterior cervical plate system • Attached to vertebral body via bone screws • Provides temporary stabilization during fusion • Screws back out prevented by passive locking mechanism	• Anterior cervical plate system • Attached to vertebral body via bone screws • Provides temporary stabilization during fusion • Screws back out prevented by passive locking mechanism	• Anterior cervical plate system • Attached to vertebral body via bone screws • Provides temporary stabilization during fusion • Screws back out prevented by passive locking mechanism
Manufacturing	• Conventional machining	• Conventional machining	• Conventional machining
Sterilization	• Moist heat	• Moist heat	• Moist heat

Non-clinical Testing

No additional non-clinical testing was required to demonstrate equivalence with the previously cleared Cardiff™ or Sonoma ACP Systems. Design Controls were used to identify any additional risks introduced by the modified device when compared with the previously submitted Cardiff™ ACP, or Sonoma ACP Systems. Engineering and Clinical rationale verified that no additional risks were introduced into the system.

Conclusions

The manufacturing process changes and instrument and implant size additions of the Cardiff Anterior Cervical Plate System have not altered the fundamental scientific technology of the previously cleared Cardiff™ ACP System, or the Sonoma ACP System. All modifications have been verified through Design Control activities and risks have been evaluated and are acceptable.

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

JAN 25 2012

SeaSpine, Inc.
% Mr. Dan W. Miller
Vice President, Quality Assurance and Regulatory Affairs
2302 La Mirada Drive
Vista, California 92081

Re: K112206
Trade/Device Name: Cardiff 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: December 22, 2011
Received: December 27, 2011

Dear Mr. Miller:

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,

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

Enclosure

K112206
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Indications for Use Statement

510(k) Number (if known): K112206

Device Name: Cardiff™

Indications for Use:

This system is indicated for use in the temporary stabilization of the anterior spine from C2 to C7 during the development of cervical spinal fusions in patients with:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- trauma (including fracture or dislocation),
- spinal stenosis,
- cervical myelopathy,
- deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudoarthrosis, and/or
- failed previous fusion.

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

510(k) Number K112206