510(K) SUMMARY

K103491

FEB 14 2011

A. Submitter Information

DePuy Spine, Inc.
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Raynham, MA 02767

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B. Date Prepared 24 November 2010

C. Device Name

Trade/Proprietary Name: SKYLINE® Anterior Cervical Plate System

Common/Usual Name: Appliance, Fixation, Spinal Intervertebral Body

Classification Name: Spinal intervertebral body fixation orthosis per 21 CFR §888.3060

D. Predicate Device Name

Trade name: SKYLINE® Anterior Cervical Plate System, cleared as the Hybrid Anterior Cervical Plate System (K052552)

E. Device Description

The SKYLINE® System consists of cervical plates and screws which are terminally sterilized via gamma radiation. Previously, these devices were commercialized as clean, but non-sterile, and the end-user would need to sterilize the units prior to use via steam sterilization. Certain screws will be packaged in sterile multi-packs for customer convenience.

F. Intended Use

The SKYLINE® Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: Instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthorosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myleopathy.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed devices are identical to the predicate devices except that the proposed devices will be terminally sterilized by DePuy Spine via gamma radiation. The design, materials, and technology remain identical to the predicate systems.

G. Materials

Manufactured from ASTM F-136 implant grade titanium alloy.

H. Biocompatibility

The sterile SKYLINE® devices do not require biocompatibility testing.

I. Conclusion

The Substantial Equivalence Justification demonstrates that the device is as safe, as effective, and performs as well as the 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

DePuy Spine, Inc.
% Mr. Frank S. Jurczak
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

FEB 14 2011

Re: K103491
Trade/Device Name: SKYLINE® 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: January 14, 2011
Received: January 18, 2011

Dear Mr. Jurczak:

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 (if known):

Device Name: SKYLINE® Anterior Cervical Plate System

Indications For Use:

The SKYLINE® Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: Instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthorosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myleopathy.

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 K103491