



Food and Drug Administration
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December 18, 2015

Stryker Spine
Ms. Soraya King
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K152532

Trade/Device Name: AERO[®]-C Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: November 23, 2015
Received: November 24, 2015

Dear Ms. King:

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 Parts 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152532

Device Name
AERO®-C Cervical Cage System

Indications for Use (Describe)

The Stryker Spine AERO®-C Cervical Cage is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc.

DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy.

The AERO®-C Cervical Cage System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach.

The AERO®-C Cervical Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine. In addition, the device must be used with the included fixation anchors.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 10: 510k Summary

510(k) Summary: AERO[®] - C Cervical Cage System	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Soraya King Regulatory Affairs Specialist Phone: 201-749-8296 Fax: 201-962-4296 Email: Soraya.King@Stryker.com
Date Prepared	November 23, 2015
Trade Name	AERO [®] -C Cervical Cage System
Proposed Class	Class II
Classification Name and Number	Intervertebral body fusion device, 21 CFR 888.3080
Product Code	ODP
Predicate Devices	<p>The AERO-C[®] Cervical Cage System was shown to be substantially equivalent to the devices listed below:</p> <p style="text-align: center;"><u>Primary Predicate</u></p> <ul style="list-style-type: none"> • Stryker Spine AVS[®] AS PEEK Spacer, K142251 & K120486 <p style="text-align: center;"><u>Additional Predicates</u></p> <ul style="list-style-type: none"> • Stryker Spine AVS[®] Anchor-C Cervical Cage System, K102606 • ORTHOVITA PEEK Cages, K072981 • Surgicraft STALIF C[®], K150053 • Synthes Zero-P, K072981 • LDR Spine ROI-C System, K091088 <p style="text-align: center;"><u>Reference Devices</u></p>

510(k) Summary: AERO[®] - C Cervical Cage System	
	<ul style="list-style-type: none"> • Stryker Spine AERO[®] -AL Lumber Cage System, K133328 • Stryker Spine AERO[®] -LL Lumbar Cage System, K142066
Device Description	<p>The AERO[®]-C Cervical Cage is a hollow, ring-shaped PEEK Optima (per ASTM F2026) cage surrounded by a titanium alloy (per ASTM F136 and ISO 5832-3) jacket. It is intended for use as an interbody fusion device and is offered in a variety of heights, widths, depths, and lordotic angles to adapt to varying patient anatomies. The PEEK Optima cage portion consists of two closed pockets for graft containment and has serrations on the superior and inferior surfaces of the cage. The implant is designed to be used with the internal supplemental fixation provided (AERO[®]-C Fixation Anchors). The AERO[®]-C Fixation Anchors are constructed from titanium alloy and possess rails that mate with dovetail channels located within the AERO[®]-C Cervical Cage. Once fully seated into the channels, the anchors are designed to lock into the titanium jacket.</p>
Indications for Use	<p>The Stryker Spine AERO[®]-C Cervical Cage is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc.</p> <p>DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy.</p> <p>The AERO[®]-C Cervical Cage System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open, anterior approach.</p>

510(k) Summary: AERO[®] - C Cervical Cage System	
	<p>The AERO[®]-C Cervical Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine. In addition, the device must be used with the included fixation anchors.</p>
Summary of the Technological Characteristics	<p>The subject AERO-C[®] implant system and the predicates share similar design features:</p> <ul style="list-style-type: none">• Graft windows for packing autogenous bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft• Serrations on the superior and inferior surfaces• Comparable heights, widths, depths, and lordotic angles• Manufactured from PEEK and Titanium Alloy

510(k) Summary: AERO[®] - C Cervical Cage System	
Summary of Non-Clinical Testing	<p>Testing in compliance with FDA’s June 12, 2007 “Class II Special Controls Guidance Document: Intervertebral Body Fusion Device” was performed for the AERO-C[®] implant system and demonstrated substantially equivalent performance to the identified predicate device systems.</p> <p>The following mechanical tests were performed:</p> <ul style="list-style-type: none"> • Static Compression (per ASTM F2077) • Dynamic Compression (per ASTM F2077) • Static Compression Shear (per ASTM F2077) • Dynamic Compression Shear (per ASTM F2077) • Static Torsion (per ASTM F2077) • Dynamic Torsion (per ASTM F2077) • Expulsion (per ASTM F04-25-02-02 Draft) • Subsidence (per ASTM F2267) • Wear Debris Assessment • Fixation Anchor Engagement Evaluation • Dynamic Cadaveric Testing involving the implantation of the AERO[®]-C device into multiple functional spinal units and subsequent evaluation of fatigue performance under multiple loading modes.
Conclusion	<p>Based upon a comparison of the design features, indications for use, technological characteristics, the use of established well-known materials, and mechanical performance, the AERO[®]-C Cervical Cage System has demonstrated substantial equivalence to the identified predicate device systems.</p>