zimmer spine	**510(k) SUMMARY** ***Optio-C™* Anterior Cervical System**

JAN 16 2014

Date of Summary Preparation: January 13, 2014

Submitter:

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Trade Name(s): *Optio-C*™ Anterior Cervical System

Device Name (Common Name): Intervertebral Fusion Device with Integrated Fixation, Cervical

Device Classification: Class II

Regulation Number and Product Code(s): 21 CFR § 888.3080 / OVE

Predicate Devices:

The *Optio-C™ Anterior Cervical System* identified several predicates to address the intended uses, mechanical functions and performance attributes of the system. The predicate information is listed in the following table:

***Optio-C* Anterior Cervical System Predicate Device Name**	**Product Code**	**FDA 510k Number Clearance Date**
Vista®-S Device Zimmer Trabecular Metal	ODP, MQP 21 CFR § 888.3080	K111983 Cleared Nov18, 2011
Trabecular Metal™ (TM-S) Zimmer Trabecular Metal	ODP 21 CFR § 888.3080	K103033 Cleared Jan 10, 2011 K111119 Cleared Nov 23, 2011
Crystal® Spinal Elements, Inc.	ODP, MQP 21 CFR § 888.3080	K073351 Cleared Jan 24, 2008
Lanx Cervical SA System Lanx, Inc.	OVE 21 CFR § 888.3080	K112388 Cleared Dec 16, 2011
HONOUR Spacer System NEXXT Spine	ODP 21 CFR § 888.3080	K120345 Cleared June 13, 2012

General Device Description:

The *Optio-C*™ *Anterior Cervical System* is comprised of an anterior cervical plate, PEEK IBF spacer and three bone screws and is intended for stand-alone cervical interbody fusion procedures at one level from C2 to T1. The subject device is used to provide structural stability in skeletally mature individuals following discectomy and is offered in multiple contours, lordotic angles, footprints and heights in order to accommodate variations in cervical anatomy.

The plate and PEEK spacer are assembled prior to implantation and placed in the disc space, flush with the adjacent vertebral bodies via an anterior surgical approach. The PEEK spacer is filled with autograft to facilitate fusion. The bone screws pass through the screw holes of the plate and affix to bone to help prevent implant migration.

The plate, with integrated anti-backout locking cap mechanism, is offered in a standard width (16mm)as a one-level configuration in multiple heights (6-12mm). The *Diamond Tip* bone screws are offered in self-drilling and self-tapping tip design, with a variable-angle and have a cortical/cancellous thread design.

The subject device can be implanted in two orientations: Standard orientation- two screws cephalic and one screw caudal or Inverted orientation- one screw cephalic and two screws caudal.

The plate and screws are also made from titanium alloy (Ti-6Al-4V ELI) per ASTM F136.The PEEK spacer is manufactured from radiolucent Polyetheretherketone (PEEK) per ASTM F2026 and contains radiographic markers comprised of Titanium Alloy (Ti-6Al-4V ELI) per ASTM F136.

The plate and PEEK spacer are supplied sterile; the bone screws and instrumentation are supplied non-sterile and are to be sterilized by the end user.

The *Optio-C*™ *Anterior Cervical System* is supplied with the instrumentation necessary for use of the system, e.g. trials, rasps, and inserters that facilitate assembly, insertion and removal of the implants.

The *Optio-C* Anterior Cervical PEEK Intervertebral Body Fusion Device (IBFD) and the *Optio-C* Anterior Cervical Plate are for single use only.

Indications for Use:

The *Optio-C™ Anterior Cervical System* includes the following Indications for Use.

***Optio-C* Anterior Cervical Intervertebral Body Fusion Device (IBFD)**

The *Optio-C* Anterior Cervical Intervertebral Body Fusion Device (IBFD) is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Degenerative disc disease (DDD) is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The *Optio-C* IBFD is comprised of one *Optio-C* PEEK IBF Spacer, one *Optio-C* Anterior Cervical Plate and three *Optio-C* bone screws.

The *Optio-C* IBFD is to be used with autograft and implanted via an open, anterior approach in patients who have had six weeks of non-operative treatment.

Summary of Technological Characteristics:

The *Optio-C* Anterior Cervical Intervertebral Body Fusion Device (IBFD) and the *Optio-C* Anterior Cervical Plate share the same technological characteristics as their predicate devices: Vista-S, Trabecular Metal (TM-S), Crystal, PEEK PREVAIL Cervical Interbody, Lanx Cervical SA System and the HONOUR Spacer. The technological characteristics include similar intended uses, mechanical and functional scientific technology, materials and the substantially equivalent performance characteristics.

The *Optio-C* Anterior Cervical Intervertebral Body Fusion Device (IBFD) and the predicates are intended to provide anterior cervical interbody fusion procedures for various indications for use, as stated in the Section above. The IBFD construction consists of a PEEK Spacer connected to a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping and/or self-drilling bone screws (with locking cap) using an anterior surgical approach. Bone screws are available for variable angle implantation. The *Optio-C* Anterior Cervical Intervertebral Body Fusion Device (IBFD) is for single use only.

The *Optio-C* Anterior Cervical Plate is a component of the Optio-C Anterior Cervical Intervertebral Body Fusion Device (IBFD) as described above.

The *Optio-C* Anterior Cervical Intervertebral Body Fusion Device (IBFD), *Optio-C* Anterior Cervical Plate and the predicates, consist of IBFD, bone screws with locking caps, and instrumentation necessary to implant the specific system.

Summary of Performance Testing:

Non-clinical testing of the components comprising each configuration of the subject *Optio-C™ Anterior Cervical System* were assessed and tested appropriately to design controls; i.e. design verification. The test results conclude the *Optio-C™ Anterior Cervical System* to be substantially equivalent to the predicate devices listed above.

- Bench Testing for the Intervertebral Body Fusion Device (IBFD) was conducted per ASTM F2077 Static and Dynamic Axial Compression, Static and Dynamic Compression Shear, Static and Dynamic Torsion and Subsidence testing per ASTM F2267; performance is acceptable for its intended use.
- Wear Testing for particulate evaluation was conducted per ASTM 1877.
- Bench Testing for the cervical plate was conducted per ASTM 1717 for Static Torsion, Static and Dynamic Compression Bending performance is acceptable for its intended use.
- Design Validation / Cadaver Testing will be conducted to ensure the *Optio-C*™ *Anterior Cervical System* performance is acceptable for its intended use and to ensure substantial equivalence to the predicate(s).
- Gamma Sterilization will be conducted for sterile implant components under ISO 11137 and ISO 11737.
- Packaging Sterility Testing will be conducted per ISO 11607 to ensure packaging materials maintain a sterile barrier.
- Sterilization is conducted for sterilizing at the end user facility under ISO 17665 and AAMI TIR12 to ensure equivalent to the predicate devices. Dry time and cleaning instructions will be assessed and yield similar (substantially Equivalent) to the predicate devices.
- Biocompatibility Assessment per ISO 10993-1 was conducted to ensure the *Optio-C* System materials are biocompatible based with the same type materials to the predicate devices.

The *Optio-C™ Anterior Cervical System* performance intended use and fundamental scientific technology remain unchanged from the predicate devices. The implant construct design does not change the stabilization fixation of the cervical vertebra found in the predicate devices. *The Optio-C™ Anterior Cervical System* is substantially equivalent to the predicate devices.

Substantial Equivalence:

Zimmer Spine considers the subject *Optio-C™ Anterior Cervical System* product performance to be substantially equivalent to the predicate devices because there is no significant difference in intended use, mechanical and functional performance and functional scientific technology. Zimmer believes no new issues of safety and effectiveness are raised due to the similarities between the subject and predicate/commercialized devices, as each are used to treat similar clinical conditions and represent a similar/basic design concept.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 16, 2014

Zimmer Spine, Incorporated
Ms. Donna Semlak
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K132894
Trade/Device Name: The Optio-C™ Anterior Cervical System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: December 10, 2013
Received: December 11, 2013

Dear Ms. Semlak:

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lori A. Wiggins

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132894

Device Name
The Optio-C™ Anterior Cervical System

Indications for Use *(Describe)*

Optio-C™ Anterior Cervical Intervertebral Body Fusion Device (IBFD)

The Optio-C™ Anterior Cervical Intervertebral Body Fusion Device (IBFD) is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Degenerative disc disease (DDD) is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Optio-C™ IBFD is comprised of one Optio-C™PEEK IBF Spacer, one Optio-C™ Anterior Cervical Plate and three Optio-C™ bone screws.

The Optio-C™ IBFD is to be used with autograft and implanted via an open, anterior approach in patients who have had six weeks of non-operative treatment.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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