DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Osseus Fusion Systems, LLC
% Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

July 3, 2017

Re: K170844
Trade/Device Name: Gemini-C Hybrid Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: June 5, 2017
Received: June 7, 2017

Dear Mr. Webb:

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 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" (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 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,

Mark N. Melkerson -S

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 below.

510(k) Number *(if known)*

K170844

Device Name

Gemini-C Hybrid Cervical Interbody System

Indications for Use *(Describe)*

The Gemini-C Hybrid Cervical Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels within the cervical spine at disc levels from C2 to T1. Degenerative disc disease (DDD) is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. This device is intended for use with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation (i.e. anterior cervical plate such as the White Pearl Preferred Angle Anterior Cervical Plate). Patients should have had at least six weeks of non-operative treatment prior to treatment with intervertebral cages.

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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510(k) Summary: Gemini-C Hybrid Cervical Interbody System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	June 5, 2017
Submitted By	Osseus Fusion Systems, LLC 2703 Mockingbird Lane, Suite 102 Dallas, TX 75235 214-395-0100 Tele email: rpace@osseus.com
Primary Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele e-mail: jdwebb@orthomedix.net
Trade Name	Gemini-C Hybrid Cervical Interbody System
Common Name	intervertebral body fusion device
Classification Name	Intervertebral body fusion device – cervical
Class	II
Product Code	ODP
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	• CONSTRUX Mini PEEK Ti Spacer System (K150619)
Additional Predicate Devices	• Crystal Cervical Cage (K073351) • Endoskeleton® TC (K100889) • BAK/Cervical Interbody Fusion (P980048) • Fusion Advantage Interbody Cages, (K083425) • Brantigan I/F Cage (P960025) • LDR Spine Cervical Interbody Fusion System (K091088) • Nanovis FortiCore™(K140280) • 4-Webb Cervical STS Interbody Fusion Device (K121741)
Device Description	The Osseus Fusion Systems' Gemini-C Hybrid Cervical Interbody System is used to maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. This system includes three design configurations: 1) PEEK, 2) Titanium alloy (Ti-6Al-4V ELI), and 3) Hybrid PEEK/Titanium alloy. The implants are available in a range of footprints and heights to suit the individual pathology and anatomical conditions of the patient. The implants have a hollow center to allow placement of bone graft.
Materials	• SOLVAY ZENIVA ZA-500 PEEK (ASTM F2026) • Ti-6A-4V ELI (ASTM F136) • Tantalum (ASTM F560) • Stainless steel (ASTM F899)

Substantial Equivalence Claimed to Predicate Devices	The Gemini-C Hybrid Cervical Interbody System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The Gemini-C Hybrid Cervical Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels within the cervical spine at disc levels from C2 to T1. Degenerative disc disease (DDD) is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. This device is intended for use with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation (i.e. anterior cervical plate such as the White Pearl Preferred Angle Anterior Cervical Plate). Patients should have had at least six weeks of non-operative treatment prior to treatment with intervertebral cages.
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic compression (ASTM F2077) • Static and dynamic compression shear (ASTM F2077) • Static and dynamic torsion (ASTM F2077) • Subsidence (ASTM F2267) • Expulsion testing (ASTM Draft Standard F-04.25.02.02) The results of these evaluations indicate that the Gemini-C Hybrid Cervical Interbody System is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Osseus Fusion Systems, LLC considers the Gemini-C Hybrid Cervical Interbody System to be equivalent to the predicate devices listed above. This conclusion is based upon the similarities between the Gemini-C and predicates in terms of principles of operation, technology, materials, and indications for use.