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

December 7, 2016

The Orthopaedic Implant Company
Douglas Fulton
Quality and Operations Manager
316 California Avenue, #701
Reno, Nevada 89509

Re: K160222
Trade/Device Name: OIC Cervical PEEK Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: October 20, 2016
Received: October 21, 2016

Dear Douglas Fulton:

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 yours,

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)*

K160222

Device Name

OIC Cervical PEEK Spacer

Indications for Use *(Describe)*

The Cervical PEEK Spacer is indicated for intervertebral body fusion of the cervical spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space. The Cervical PEEK Spacer is intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The Cervical PEEK Spacer is intended to be used with a supplemental internal fixation system.

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

Prepared 12/5/2016

Name and Address of Manufacturer:
The Orthopaedic Implant Company (OIC)
770 Smithridge Dr, Suite 400
Reno, NV 89502

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Email: doug@orthoimplantcompany.com

Device Identification:
Trade Name: OIC Cervical PEEK Spacer
Classification Name: Intervertebral body fusion device
Classification: Class II, 21 CFR 888.3080
Panel: Orthopedic
Product Code: ODP

Indications for Use:
The Cervical PEEK Spacer is indicated for intervertebral body fusion of the cervical spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space. The Cervical PEEK Spacer is intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The Cervical PEEK Spacer is intended to be used with a supplemental internal fixation system.

Device Description:
The Cervical PEEK Spacer is a polyetheretherketone cervical interbody fusion spacer. The device comprises a closed annular ring and hollow center for placement of bone graft and sawtooth “teeth” on the inferior and superior surfaces for resisting migration and expulsion. The device includes a radiopaque marker pin positioned within the central posterior wall of the device. The device is offered in two footprints (depth x width, 9.5mm x 12mm and 10.5mm x 15mm), one lordotic angle (7°) and heights ranging from 6mm to 10mm in 1mm increments.

Comparison of Technological Characteristics (Substantial Equivalence):
Predicate device - K092540 InterPlate C-PS Interbody Spacers
The modified Cervical PEEK Spacer has the following similarities to those which previously received 510(k) concurrence:
· have the same indicated use,
· use the same operating principle,
· incorporate the same design,
· incorporate the same materials,
· have the same shelf life, and
· are packaged using the same materials and processes.
Additional Predicate device - K111272 Rhausler Plage Anterior Cervical Fusion System
The materials, geometry and use of the instruments for implantation are the same as the instruments in the secondary predicate device.

Performance Testing:
Static axial compression, dynamic axial compression, static torsion and dynamic torsion testing per ASTM F 2077-03 and subsidence testing per ASTM F 2267-04 were performed on representative samples of the device. The Cervical PEEK Spacers were found to have acceptable mechanical characteristics for the intended uses.

Conclusion:
The OIC Cervical PEEK Spacer described in this submission is, in our opinion, substantially equivalent to the predicate devices.