DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 12, 2016

SPINEART
Mr. Franck Pennesi
Director of Industry & Quality
International Center Cointrin
20 Route De Pré-bois CP1813
1215 Geneva, 15
SWITZERLAND

Re: K161888
Trade/Device Name: JULIET® LL Lateral Lumbar Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 12, 2016
Received: August 15, 2016

Dear Mr. Pennesi:

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 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,

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)*
K161888

Device Name
JULIET® LL Lateral Lumbar Cage

Indications for Use *(Describe)*
JULIET®LL Lumbar Interbody Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft. JULIET®LL Lumbar Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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)*

510(k) SUMMARY

Submitted by	**SPINEART** International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
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Date Prepared	September 7th 2016
Common Name	Intervertebral body fusion device
Trade Name	JULIET® LL Lateral Lumbar Cage
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Class	II
Product Code	MAX
CFR section	888.3080
Device panel	ORTHOPEDIC
Legally marketed predicate device	Primary predicate: JULIET® LL (K141135) manufactured by Spineart
Indications for use	JULIET®$_{LL}$ Lumbar Interbody Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft. JULIET®$_{LL}$ Lumbar Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Description of the device	The JULIET®LL Titanium Lateral Lumbar cages are rectangle-shaped intervertebral body fusion devices with a central cavity that can be filled with bone graft (autograft) to facilitate fusion. The JULIET®LL intervertebral body fusion spacer comes in various sizes and footprints in order to fulfill surgeons' needs and accommodate different patient anatomies. The JULIET®LL system is made of Titanium Ti 6Al-4V ELI conforming to ASTM F136 and ISO 5832-3. The JULIET® LL Titanium Lateral Lumbar cages are supplied with dedicated surgical instruments (reusable – provided non sterile).
Technological Characteristics	The modification to JULIET®LL Titanium Lateral Lumbar cages consists of the addition of lordotic version of the range of existing spacers having a width of 17 mm, a height ranging from 08 to 16 mm, and a length ranging from 40 to 60 mm.
Discussion of Testing	The following non-clinical tests were initially conducted on JULIET®LL Titanium Lateral Lumbar cages (K141135): Static axial compression, Static shear compression according to ASTM F2077 and subsidence testing according to ASTM F2267. A rationale based on verification activity and validation activity demonstrate that the devices added to the JULIET®LL Titanium Lateral Lumbar range of products are as safe, as effective, and performs at least as safely and effectively as predicate JULIET®LL Titanium Lateral Lumbar cages (K141135). No additional testing has been performed. Bacterial endotoxin testing as specified in USP <85> standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device.
Conclusion	The extended range of JULIET®LL Titanium Lateral Lumbar cages is substantially equivalent to its predicate devices in terms of intended use, labeling, material, design, mechanical properties and function. Verification Activity and Validation Activity demonstrate that the added devices are as safe, as effective, and perform at least as safely and effectively as its predicates (K141135).