SPINEART
Franck Pennesi
Chief Technical Officer
3 Chemin du Pré Fleuri
1228 PLAN LES OUATES
GENEVA SWITZERLAND

January 3, 2018

Re: K173702
Trade/Device Name: Juliet® Ti LL
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 1, 2017
Received: December 4, 2017

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 (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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

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 below.

510(k) Number *(if known)*
K173702

Device Name
Juliet® Ti LL

Indications for Use *(Describe)*
JULIET® Ti 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® Ti 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510k
Juliet® Ti LL

510(k) SUMMARY

510k	SPECIAL
Basis for submission	Extension of the range of Juliet® Ti devices
Submitted by	SPINEART 3 Chemin du Pré Fleuri 1228 PLAN LES OUATES GENEVA SWITZERLAND
Contacts	Franck PENNESI Chief Technical Officer Phone : +41 22 570 1200 Fax : +41 22 594 8306 Mail : fpennesi@spineart.com Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Date Prepared	January 03, 2018
Common Name	Intervertebral body fusion device
Trade Name	Juliet® Ti LL
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Class	II
Product Code	MAX
CFR section	888.3080
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary predicate: Juliet® Ti (K153621) manufactured by Spineart Additional predicates: Juliet® LL (K161888, K141135) manufactured by Spineart
Indications for use	JULIET® Ti 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® Ti 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	Spineart Juliet® Ti LL spinal implants consist of a range of titanium intervertebral body spacers, implanted via a lateral approach, with various sizes and footprints so as to adapt different patient's conditions. The Juliet® Ti LL spinal implants are made of Titanium alloy Ti6Al4V ELI conforming to ASTM F136. The Juliet® Ti LL spinal implants are additively manufactured and present both solid and porous structures. The subject implants Juliet® Ti LL will extend the previously cleared Juliet® Ti (PO, OL & TL) range of implants (K153621) which presents similar design features and the same manufacturing technology, i.e. additive manufacturing (SLM) and will join the previously cleared Juliet® LL range of implants (K161888; K141135) which presents similar design features and addresses the same surgical approach and utilize the same instrumentation designed purposely. The Juliet® Ti LL spinal implants are delivered sterile (gamma sterilization) and supplied with dedicated surgical instruments (reusable – provided non-sterile).
Technological characteristics compared to the predicate devices	The Juliet® Ti LL spinal implants are manufactured using the same manufacturing technology, i.e. additive manufacturing (SLM) as predicate device Juliet® Ti (PO, OL & TL). The characterization of the chemical, physical and mechanical properties of the material was performed in accordance with ASTM F3001 and ASTM E8/E8M. The porous structure featured on titanium alloy implants additively manufactured was validated based on the FDA's Guidance for industry on the testing of metallic plasma sprayed coatings on orthopedic implants to support reconsideration of postmarket surveillance requirements. The Juliet® Ti LL spinal implants present a similar design feature and range of devices as the previously cleared Juliet® LL spinal implants. Both Juliet® Ti LL and Juliet® LL are designed for a lateral approach. The following non-clinical tests were conducted on the predicate devices: Static and dynamic axial compression, static and dynamic shear compression according to ASTM F2077 and subsidence testing according to ASTM F2267. A Finite Element Analysis has been submitted to support substantial equivalence. Bacterial endotoxin testing as specified in USP standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device.
Discussion of Testing	No additional testing has been performed for the Spineart Juliet® Ti LL spinal implants.
Conclusion	Based on the design features, technological characteristics, feature comparisons, and indications for use, Juliet® Ti LL has demonstrated substantial equivalence to the identified predicate devices.