May 29, 2019

Spineart
Mr. Franck Pennesi
Chief Technical Officer
3 chemin du pre Fleuri
Plan Ouates, 1228 Ch

Re: K190877
Trade/Device Name: Juliet® Ti LL Lumbar Interbody Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: April 2, 2019
Received: April 4, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

for
CAPT Raquel Peat, PhD, MPH, USPHS
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190877

Device Name
JULIET® Ti LL Lumbar Interbody Device

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). The JULIET® Ti LL Lumbar Interbody Device are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.
Implants with 15-degree lordosis or greater are only indicated from levels L2-L5 and are to be used with at least two integrated fixation screws. The JULIET® Ti LL implants must be used with supplemental internal spinal fixation system that has been cleared by the FDA for use in the lumbosacral spine.

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

510k	TRADITIONAL
Basis for submission	NEW DEVICES –LINE EXTENSION
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	March 26, 2019
Common Name	Intervertebral body fusion device
Trade Name	JULIET® Ti LL Lumbar Interbody Device
Classification Name	Intervertebral Fusion Device with Integrated Fixation Lumbar / Intervertebral Fusion Device Lumbar
Class	II
Product Code	OVD / MAX
CFR section	888.3080
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary predicate: Scarlet® AL-T (K181818) manufactured by Spineart Additional predicates: Juliet® Ti LL (K173702) manufactured by Spineart and Timberline® MPF (K163543) manufactured by Zimmer Biomet
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). The JULIET® Ti LL Lumbar Interbody Device are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. Implants with 15-degree lordosis or greater are only indicated from levels L2-L5 and are to be used with at least two integrated fixation screws. The JULIET® Ti LL implants must be used with supplemental internal spinal fixation system that has been cleared by the FDA for use in the lumbosacral spine.

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 Product Line Extension consists of an extended range of titanium alloy spacers with integrated fixation. Juliet® Ti LL Product Line Extension also introduces a range of hyperlordotic intervertebral spacers of various sizes, heights, footprints and lordosis with the integrated fixation. The Juliet® Ti LL spinal implants are delivered sterile (gamma sterilization) and supplied with dedicated surgical instruments (reusable – provided non-sterile). Bacterial endotoxin testing as specified in USP standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device.
Technological characteristics compared to the predicate devices	The added Juliet® Ti LL implants present similar design features, solid, lattice and porous structures, the same manufacturing technology, i.e. additive manufacturing (SLM) and the same material, i.e. titanium alloy conforming to ASTM F136 identically to Juliet® Ti LL (K173702). The previously cleared Juliet® Ti LL (K173702) and added hyperlordotic interbody spacers can be implanted in a configuration with integrated fixation provided by the mean of titanium alloy plate that come in various shapes, and heights and fixation screws that come in various diameters and lengths so as to better fulfil surgeon's needs and to accommodate varying patient anatomy. The bone screws are secured by the mean of a cover-plate that prevent backing out. Juliet® Ti LL implants conform to the Guidance for Industry and Food and Drug Administration Staff issued on December 5, 2017 "Technical Considerations for Additive Manufactured Devices". As was established in this submission added Scarlet® AC-T fixation screws are substantially equivalent and has the same technological and mechanical characteristics to predicate devices.
Discussion of Testing	The following non-clinical tests were conducted on the Juliet® Ti LL: static and dynamic axial compression (per ASTM F2077), static and dynamic shear compression (per ASTM F2077), static and dynamic torsion (per ASTM F2077), expulsion, subsidence (per ASTM F2267) and mass loss determination after dynamic testing on assemblies (spacer + plate + fixation screws) that passed 5 million cycles. Results demonstrate comparable mechanical properties to the primary predicate device Scarlet® AL-T (K181818) manufactured by Spineart. Additionally, axial push out on the fixation screws through the plate has been conducted.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the added Juliet® Ti LL devices have demonstrated substantial equivalence to the identified predicate devices.