DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 15, 2016

SPINEART
Mr. Franck Pennesi
Director of Industry & Quality
International Center Cointrin
20, route de Pré-Bois - CP1813
1215 Geneva,
SWITZERLAND

Re: K153621
Trade/Device Name: Juliet® Ti
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 13, 2016
Received: June 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 (21 CFR 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 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)*
K153621

Device Name
Juliet® Ti

Indications for Use *(Describe)*

Juliet® Ti PO, OL & TL lumbar interbody devices are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine 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 and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Juliet® Ti lumbar interbody devices are to be used with supplemental fixation that has been cleared for use in the lumbosacral spine. 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)*

Zane W. Wyatt
Division of Orthopedic Devices

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510k
JULIET® Ti

510(k) SUMMARY

Submitted by	SPINEART International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 570 1246 Fax : +41 22 799 4026 Mail : fpennesi@spineart.com Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) Mail : idrubaix@nordnet.fr
Date Prepared	June 13, 2016
Common Name	Intervertebral body fusion device
Trade Name	JULIET® Ti
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: Cascadia Interbody System (K150481) manufactured by K2M, Inc Additional predicates: Dynamik intervertebral body fusion device (renamed Juliet) (K081888) manufactured by Spineart; JULIET PO (K142277) manufactured by Spineart; Capstone Control Spinal System (K120368) manufactured by Medtronic Sofamor Danek Usa, In; Capstone Spinal System (K133650) manufactured by Medtronic Sofamor Danek Usa, In; LUCENT (K071724) manufactured by Spinal Elements, Inc

Indications for use	Juliet® Ti PO, OL & TL lumbar interbody devices are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine 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 and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Juliet® Ti lumbar interbody devices are to be used with supplemental fixation that has been cleared for use in the lumbosacral spine. 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 PO, OL & TL spinal implants consist of a range of intervertebral body spacers with various shapes and designs so as to be implanted via an open posterior or transforaminal approach and to adapt different patient's conditions. Spineart JULIET® Ti cage is offered in a variety of lengths, heights, widths and lordotic angles to adapt to a variety of patient anatomies. Juliet® Ti PO, OL & TL spinal implants are made of Titanium alloy Ti6Al4V ELI conforming to ASTM F136. Juliet® Ti PO, OL & TL spinal implants are additively manufactured and present both solid and porous structures. The Juliet® Ti cages are delivered sterile (gamma sterilization) and supplied with surgical instruments (reusable – provided non-sterile).
Summary of Technological Characteristics	The subject JULIET® Ti device is identical in indications for use, surgical technique, manufacturing method and raw material to the predicate device cleared in K150481. The subject JULIET® Ti device shares similar design features, comparable heights, widths, depths, lordotic angles and surgical instrumentation as the predicate devices (K081888, K142277, K120368, K133650, K071724).
Discussion of Testing	Testing in compliance with: FDA's "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the JULIET® Ti Cages and demonstrated substantially equivalent performance to the identified predicate devices. The following mechanical tests were performed: Static and dynamic axial compression (per ASTM F2077), Static and dynamic Shear compression (per ASTM F2077), Subsidence (per ASTM F2267) 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 performed 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 following tests were performed: Static shear strength (per ASTM F1044), Fatigue shear strength (per ASTM F1160) Static tensile strength (per ASTM F1147) and abrasion resistance (per ASTM F1978).
Conclusion	Based on the design features, the use of established well known materials, feature comparisons, indications for use, and results of the mechanical testing, the JULIET® Ti has demonstrated substantial equivalence to the identified predicate devices.