July 24, 2024

Spineart SA
Estelle Lefeuvre
Regulatory & Market Access Manager
3 Chemin Du Pré-Fleuri
Plan Les Ouates, 1228
Switzerland

Re: K241321
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

Dear Estelle Lefeuvre:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 18, 2024. Specifically, FDA is updating this SE Letter to include a valid digital signature with FDA watermark as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Brent Showalter, Ph.D., OHT6: Office of Orthopedic Devices, (240) 402-1840, Brent.Showalter@fda.hhs.gov.

Sincerely,

Aakash Jain -S

for Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

July 18, 2024

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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: May 10, 2024
Received: May 10, 2024

Dear Estelle Lefeuvre:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Brent Showalter, Ph.D.
Assistant 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241321

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.

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.

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Food and Drug Administration
Office of Chief Information Officer
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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."

510(k) Summary

Prepared on: 2024-07-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	SPINEART SA
Applicant Address	3 chemin du Pré-Fleuri PLAN LES OUATES 1228 Switzerland
Applicant Contact Telephone	+41 22 570 1203
Applicant Contact	Ms. ESTELLE LEFEUVRE
Applicant Contact Email	elefeuvre@spineart.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Juliet® Ti LL Lumbar Interbody Device
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Regulation Number	888.3080
Product Code(s)	OVD, MAX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190877	Juliet® Ti LL	OVD
K173702	Juliet® Ti LL	MAX

Device Description Summary

21 CFR 807.92(a)(4)

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 Juliet® Ti LL spinal implants are delivered sterile (gamma sterilization). Bacterial endotoxin testing as specified in USP standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device.

The purpose of this submission is to add a new height (10mm) for the hyperlordotic spacers (five footprints) with a lordosis of 15° to the previously cleared Juliet® Ti LL range of devices (K190877, K173702).

The design of the connection interface of the cage, the plates and the screws are not modified. The solid, lattice and porous structures are the same. No modifications have been made to the intended use, indications for use, materials, manufacturing process, sterilization process.

Previously cleared (K190877, K173702) and added Juliet® Ti LL implants conform to Class II special controls established for Sec 888.3080 Intervertebral body fusion device.

Additionally, the Juliet Ti LL package insert has been updated to describe the conditions under which patients can be safe within an MR environment.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The added Juliet® Ti LL interbody spacers subject of this submission have the same indication for use as the predicate Juliet® Ti LL devices cleared under K190877.

Technological Comparison 21 CFR 807.92(a)(6)

The purpose of this submission is to add a new height (10mm) for the hyperlordotic spacers (five footprints) with a lordosis of 15° to the previously cleared Juliet® Ti LL range of devices (K190877, K173702).
The design of the connection interface of the cage, the plates and the screws are not modified. The solid, lattice and porous structures are the same. No modifications have been made to the intended use, indications for use, materials, manufacturing process, sterilization process.
Previously cleared (K190877, K173702) and added Juliet® Ti LL implants conform to Class II special controls established for Sec 888.3080 Intervertebral body fusion device.

Additionally, the Juliet Ti LL package insert has been updated to describe the conditions under which patients can be safe within an MR environment.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The present submission introduces only additional references for the interbody spacer. The interbody spacer interface connection, the plates and the screws are not impacted by the product line extension.
The following non-clinical tests were conducted on Juliet® Ti LL predicate devices (#K173702 / #K190877):
- 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.

Additionally, axial push out on the fixation screws through the plate were conducted.
The engineering analysis has demonstrated that that Juliet® Ti LL line extension (present submission) does not introduce new worst cases regarding the mechanical testing, so the tests performed on Juliet® Ti LL predicate devices (K173702 / K190877) are still valid and cover the added cage references.

Standards for MR assessments are the following:
- Magnetically induced displacement force (ASTM F2052).
- Magnetically induced torque (ASTM F2213).
- MR image artifact (ASTM F2119).
- Radiofrequency (RF) induced heating (ASTM F2182).
- Standard practice for marking medical devices and other items for safety in the magnetic resonance environment (ASTM F2503)
- Testing and labeling medical devices for safety in the magnetic resonance environment (Guidance for Industry and FDA Staff, October 10, 2023

There is no significant difference between the Juliet® Ti LL line extension (present submission) and the previously cleared Juliet® Ti LL predicate devices (K173702 / K190877) which would adversely affect the use and performances of the product or raise any issue of safety and effectiveness. Consequently, no new mechanical tests were carried out.
The subject Juliet® Ti LL devices are substantially equivalent to the previously cleared Juliet® Ti LL devices (K190877, K173702) with respect to their intended use, indications for use, device description, technological characteristics, and performance. The information provided in this premarket submission supports substantial equivalence to the predicate devices (K190877, K173702).