



Spineart
Franck Pennesi
Chief Technical Officer
3 Chemin du Pré Fleuri
1228 Plan Les Ouates
Geneva, Switzerland

October 9, 2018

Re: K181818
Trade/Device Name: Scarlet® AL-T
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: September 12, 2018
Received: September 13, 2018

Dear Franck 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,


Brent Showalter -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181818

Device Name

Scarlet® AL-T

Indications for Use (Describe)

The Scarlet® AL-T system is 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 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.

When used with the integrated fixation by the mean of the bone screws provided, the Scarlet® AL-T is a stand-alone system and requires no additional supplemental fixation system.

When used as a lumbar intervertebral fusion device (i.e. without the bone screws provided), the Scarlet® AL-T interbody device 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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**Traditional 510k
SCARLET® AL-T**

510(k) SUMMARY

510k	TRADITIONAL
Basis for submission	NEW 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	July 2, 2018
Common Name	Intervertebral body fusion device
Trade Name	Scarlet® AL-T
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	<u>Primary predicate:</u> Renovis S134 Anterior Lumbar Interbody Fusion (ALIF) System manufactured by Renovis Surgical Technologies, Inc (K142095) <u>Additional predicates:</u> Centinel Spine STALIF TT, STALIF MIDLINE, MIDLINE II, MIDLINE II-Ti manufactured by Centinel Spine, Inc (K150643), VU APOD Intervertebral Body Fusion Device Manufactured by Theken Spine, LLC (K101310, K121211) and Juliet® Ti manufactured by Spineart (K153621)
Indications for use	The Scarlet® AL-T system is 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 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. When used with the integrated fixation by the mean of the bone screws provided, the Scarlet® AL-T is a stand-alone system and requires no additional supplemental fixation system. When used as a lumbar intervertebral fusion device (i.e. without the bone screws provided), the Scarlet® AL-T interbody device 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	The Scarlet® AL-T spinal system is an anterior lumbar interbody fusion device with integrated fixation intended to provide mechanical support to the lumbar spine and maintain adequate disc space until fusion occurs. The Scarlet® AL-T system comprises a range of intervertebral spacers implanted via an anterior approach, and having various sizes, heights, footprints and lordosis so as to adapt individual pathology and different patient's anatomical conditions. The interbody device is a box-shaped spacer with a large central cavity that can receive bone graft intended to promote intervertebral fusion. The Scarlet® AL-T spacers are all made from medical grade titanium alloy conforming to ASTM F136 standard and are produced by additive manufacturing (SLM) according to ASTM F3001. Subsequently the spacer is machined (thread tapping) and polished. The Scarlet® AL-T interbody spacer has a monolithic design that incorporates solid, lattice and porous structures along with superior and inferior rough surfaces intended to increase implant stability into the intervertebral space and bony integration throughout the implant. When used as a stand-alone system with its integrated fixation, the spacer is crossed by three (3) bone screws protruding into the vertebral endplates. The bone screws are secured by the mean of two (2) cam locks that prevent backing out. The Scarlet® AL-T 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 Scarlet® AL-T implants are manufactured using the same manufacturing technology, i.e. additive manufacturing (SLM) as predicate device Juliet® Ti (K153621). 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.
Discussion of Testing	The following non-clinical tests were conducted on the Scarlet® AL-T: Static and dynamic axial compression (per ASTM F2077-17), Static and dynamic Shear compression (per ASTM F2077-17) expulsion (per ASTM Draft F-04.25.02.02) and subsidence (per ASTM F2267-04). Results demonstrate comparable mechanical properties to the predicate devices. Bacterial endotoxin testing as specified in USP standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the Scarlet® AL-T has demonstrated substantial equivalence to the identified predicate devices.