January 22, 2020

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

Re: K192993
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: October 22, 2019
Received: October 25, 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/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 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 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, PhD
Assistant Director (Acting)
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)*
K192993

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.

The Scarlet® AL-T Hyperlordotic (≥ 20°) cages are to be used with BOTH the integrated fixation by the mean of the bone screws provided and ALSO additional supplemental 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.

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."

K192993
510(k) SUMMARY

510k	TRADITIONAL
Basis for submission	New devices - Product 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	December 19, 2019
Common Name	Intervertebral body fusion device
Trade Name	Scarlet® AL-T
Classification Name	Intervertebral Fusion Device with Integrated Fixation Lumbar
Class	II
Product Code	OVD
CFR section	888.3080
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary predicate: Scarlet® Al-T manufactured by Spineart (K181818) Additional predicate: NuVasive BASE Interfixated Titanium System manufactured by NuVasive, Incorporated (K170592)
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. The Scarlet® AL-T Hyperlordotic (≥ 20°) cages are to be used with BOTH the integrated fixation by the mean of the bone screws provided and ALSO additional supplemental 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 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). 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 subject product line extension consists of an extended range of titanium alloy spacers intended to be used with the three unicortical cancellous bone screws previously approved (K181818). Scarlet® AL-T product line extension comprises a range of hyperlordotic 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 Scarlet® AL-T Hyperlordotic (≥ 20°) cages are to be used with BOTH the integrated fixation by the mean of the bone screws provided and ALSO additional supplemental fixation system that has been cleared by the FDA for use in the lumbosacral spine. Except for the lordosis, the Scarlet® AL-T hyperlordotic implants present the same design features, anti-backout mechanism, integrated fixation and bone screws as the cleared Scarlet® AL-T devices (K181818). The Scarlet® AL-T hyperlordotic implants are manufactured using the same manufacturing technology, i.e. additive manufacturing (SLM) as predicate device Scarlet® AL-T (K181818). Except for the dedicated trial devices and implant holder, the Scarlet® AL-T hyperlordotic implants share the same surgical instrumentation as predicate device Scarlet® AL-T (K181818).
Discussion of Testing	The following non-clinical tests were conducted on the Scarlet® AL-T hyperlordotic cages: Static Axial Compression according to ASTM F2077-18, Static Shear-compression according to ASTM F2077-18; Static Torsion according to ASTM F2077-18, Subsidence according to ASTM F2267-04 and Expulsion according to ASTM Draft F-04.25.02.02. Results demonstrate comparable mechanical properties to the predicate device Scarlet® AL-T (K181818). Based on the static testing results and engineering analysis it has been determined that dynamic testing was not necessary.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the Scarlet® AL-T hyperlordotic cages have demonstrated substantial equivalence to the identified predicate devices.