October 23, 2024

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

Re: K242589
Trade/Device Name: Scarlet® AL-T
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: August 30, 2024
Received: August 30, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Brent Showalter -S

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)*

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.

510(k) #:

510(k) Summary

Prepared on: 2024-08-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Spineart SA
Applicant Address	Chemin du Pré-Fleuri 3 Plan-les-Ouates 1228 Switzerland
Applicant Contact Telephone	0041225701203
Applicant Contact	Mrs. Estelle Lefeuvre
Applicant Contact Email	elefeuvre@spineart.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SCARLET® AL-T
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Regulation Number	888.3080
Product Code(s)	MAX, OVD

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K181818	SCARLET® AL-T	MAX
K192993	SCARLET® AL-T	OVD

Device Description Summary

21 CFR 807.92(a)(4)

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.

The purpose of this submission is to add a 5° range of lordotic intervertebral spacers in 3 footprints (small, medium, & large) and a 20mm

height to the existing 10° and 15° footprints to the previously cleared SCARLET® AL-T range of devices (K181818, K192993).
The solid, lattice and porous structures of the cages are the same. No modifications have been made to the intended use, indications for use, materials, manufacturing process, sterilization process.
Previously cleared (K181818, K192993) and added SCARLET® AL-T implants conform to Class II special controls established for Sec 888.3080 Intervertebral body fusion device.
Additionally, the SCARLET® AL-T package insert has been updated to ensure safety in the magnetic resonance (MR) environment.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The added SCARLET® AL-T interbody spacers subject of this submission have the same indication for use as the predicate SCARLET® AL-T devices cleared under K181818.

Technological Comparison

21 CFR 807.92(a)(6)

The purpose of this submission is to add a 5° range of lordotic intervertebral spacers in 3 footprints (small, medium, & large) and a 20mm height to the existing 10° and 15° footprints to the previously cleared SCARLET® AL-T range of devices (K181818, K192993).
The solid, lattice and porous structures of the cages are the same. No modifications have been made to the intended use, indications for use, materials, manufacturing process, sterilization process.
Previously cleared (K181818, K192993) and added SCARLET® AL-T implants conform to Class II special controls established for Sec 888.3080 Intervertebral body fusion device.
Additionally, the SCARLET® AL-T package insert has been updated to ensure safety in the magnetic resonance (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 and trials.
The following non-clinical tests were conducted on SCARLET® AL-T predicate devices (#K181818/ #K192993):
- 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 that passed 5 million cycles.

The engineering analysis has demonstrated that that SCARLET® AL-T line extension (present submission) does not introduce new worst cases regarding the mechanical testing, so the tests performed on SCARLET® AL-T predicate devices (K181818 / K192993) are still valid and cover the added cage references.

There is no significant difference between the SCARLET® AL-T line extension (present submission) and the previously cleared SCARLET® AL-T predicate devices (K181818 / K192993) 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.