May 10, 2024

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

Re: K240699
Trade/Device Name: SCARLET® AC-Ti
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: March 12, 2024
Received: March 14, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240699

Device Name
SCARLET® AC-Ti

Indications for Use *(Describe)*
SCARLET® AC-Ti cages are indicated for use in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. SCARLET® AC-Ti cages are intended to be used at one or two contiguous levels from C2-T1 to facilitate intervertebral body fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used with two bone screws, the SCARLET® AC-Ti Secured Anterior Cervical Cage is intended to be used as a standalone system and requires no additional supplementary fixation systems.

When used with two anchors or without two bone screws, the SCARLET® AC-Ti cages are to be used with supplemental fixation which has been cleared by the FDA for use in the cervical spine.

The SCARLET® AC-Ti hyperlordotic (12° lordosis) cages are to be used with bone screws and/or anchors and additional supplemental fixation system that has been cleared by the FDA for use in the cervical 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."

Traditional 510k
SCARLET® AC-Ti

510(k) SUMMARY

510k	Traditional
Basis for submission	New devices
Submitted by	SPINEART SA 3 Chemin du Pré Fleuri 1228 Plan-les-Ouates SWITZERLAND
Contacts	Max LOK, EVP RAQA Phone : +41 22 570 1200 Fax : +41 22 594 8306 Mail : mlok@spineart.com Regulatory contact : Estelle LEFEUVRE (elefeuvre@spineart.com)
Date Prepared	May 2nd, 2024
Common Name	Intervertebral body fusion device
Trade Name	SCARLET® AC-Ti
Classification Name	Intervertebral Fusion Device With Integrated Fixation, Cervical
Class	II
Product Code	OVE, ODP
CFR section	888.3080
Device panel	Orthopedic
Legally marketed predicate devices	Primary predicate: SCARLET® AC-T Secured Anterior Cervical Cage manufactured by Spineart (K141314, K143214, K172065, K190322) Additional predicates: - TRYPTIK® Ti manufactured by Spineart (K200312, K230583) - ChoiceSpine Blackhawk Ti Cervical Spacer System manufactured by ChoiceSpine LLC (K203311, K223869) - Atlas Spine Expandable Cervical Standalone Interbody System manufactured by Atlas Spine, Inc. (K192570)

Indications for use	SCARLET® AC-Ti cages are indicated for use in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. SCARLET® AC-Ti cages are intended to be used at one or two contiguous levels from C2-T1 to facilitate intervertebral body fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used with two bone screws, the SCARLET® AC-Ti Secured Anterior Cervical Cage is intended to be used as a standalone system and requires no additional supplementary fixation systems. When used with two anchors or without two bone screws, the SCARLET® AC-Ti cages are to be used with supplemental fixation which has been cleared by the FDA for use in the cervical spine. The SCARLET® AC-Ti hyperlordotic (12° lordosis) cages are to be used with bone screws and/or anchors and additional supplemental fixation system that has been cleared by the FDA for use in the cervical spine.
Description of the device	Spineart SCARLET® AC-Ti system is a Cervical Intervertebral Body Fusion device with integrated fixation intended to provide mechanical support and stabilization to the cervical spine and maintain adequate disc space until fusion occurs. The system comprises a range of intervertebral spacers implanted via an anterior approach, and having various sizes, heights, footprints, and lordosis to adapt individual pathology and different patients' anatomical conditions. The interbody device is a box-shaped spacer with a central cavity that can receive bone graft, which is intended to promote intervertebral fusion. It has a monolithic design and is crossed by two tunnels that guide the bone screws and/or the anchors insertion into the vertebral endplates. Moreover, SCARLET® AC-Ti comprises integrated fixation by the mean of bone screws and/or anchors that come in various diameters and lengths. The SCARLET® AC-Ti spacers are all made from medical grade titanium alloy conforming to ASTM F136 and are produced by additive manufacturing (SLM) according to ASTM F3001. Subsequently the spacer is polished and thread tapping is machined. The screws and anchors are made from Ti-6Al-4V ELI conforming to ASTM F136. The SCARLET® AC-Ti spinal implants are delivered sterile (gamma sterilization) and supplied with dedicated surgical instruments (reusable – provided non-sterile). Bacterial endotoxin testing on final, finished devices as specified in USP standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device.

Spineart SA | Chemin du Pré Fleuri 3 | 1228 PLAN-LES-OUATES | SUISSE | Phone +41 (0)22 570 12 00 | Fax +41 (0)22 594 83 06 | www.spineart.com

Technological characteristics compared to the predicate devices	The SCARLET® AC-Ti spinal implants are manufactured using the same manufacturing technology, i.e. additive manufacturing (SLM) as predicate device TRYPTIK® Ti. The characterization of the chemical, physical and mechanical properties of the material was performed in accordance with ASTM F3001. The SCARLET® AC-Ti implants are available in various sizes, heights, footprints and lordosis so as to adapt individual pathology and different patient's anatomical conditions. The SCARLET® AC-Ti implants are implanted via an anterior approach. These features are similar to those of the predicate devices (K141314, K143214, K172065, K190322, K200312, K230583, K223869, K203311, K192570)
Discussion of Testing	**Mechanical testing:** Static and dynamic Axial Compression, Static and dynamic Shear-compression and Static and dynamic Torsion according to ASTM F2077-22 and Subsidence according to ASTM F2267-22 were conducted. Results demonstrate comparable mechanical properties to the identified predicate devices. Mass loss was measured on post-test run out SCARLET® AC-Ti worst-case specimens dynamically tested. Expulsion characterization was conducted. **MRI Safety Evaluation:** In accordance with the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" (Issued October 2023), testing has been completed on the worst-case implants. The following testing has been completed and provided a determination that the subject Spineart SCARLET® AC-Ti in this 510(k) submission has been determined to be MR conditional: - ASTM F2052-2021: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment - ASTM F2213-17: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment - ASTM F2119-07: Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants - ASTM F2182-19e2: Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance - ASTM F2503-23e1:"Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment" **Human cadaveric testing:** Cadaver lab trials were conducted.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the SCARLET® AC-Ti implants have demonstrated substantial equivalence to the identified predicate devices.

Spineart SA | Chemin du Pré Fleuri 3 | 1228 PLAN-LES-OUATES | SUISSE | Phone +41 (0)22 570 12 00 | Fax +41 (0)22 594 83 06 | www.spineart.com