March 4, 2019

SPINEART
Franck Pennesi
Chief Technical Officer
3 Chemin du Pre Fleuri
Plan Les Ouates
CH 1228 Geneva

Re: K190322
Trade/Device Name: SCARLET® AC-T Secured Anterior Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: February 11, 2019
Received: February 13, 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/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,

Melissa Hall -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K190322

Device Name
SCARLET® AC-T Secured Anterior Cervical Cage

Indications for Use *(Describe)*
SCARLET® AC-T 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-T cages are intended to be used at one level from the C2-C3 disc to the C7-T1 disc to facilitate intervertebral body fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.
The SCARLET® AC-T Secured Anterior Cervical Cage is intended to be used as a standalone system used with the two bone screws provided and requires no additional supplementary fixation systems. When used without the two bone screws, SCARLET AC-T cages are to be used with supplemental fixation which 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.

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SPECIAL 510k DEVICE MODIFICATION
Scarlet® AC-T

510(k) SUMMARY

510k	510k SPECIAL – DEVICE MODIFICATION
Reason for submission	Extension of the range of SCARLET® AC-T screws
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	February 8, 2019
Common Name	Intervertebral body fusion device
Trade Name	SCARLET® AC-T Secured Anterior Cervical Cage
Classification Name	Intervertebral fusion device with bone graft, cervical / Intervertebral fusion device with integrated fixation, cervical
Class	II
Product Code	ODP / OVE
CFR section	888.3080
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary predicate: SCARLET® AC-T Secured Anterior Cervical Cage (K172065) manufactured by SPINEART Additional predicates: SCARLET® AC-T Secured Anterior Cervical Cage (K143214 and K141314) manufactured by SPINEART

Indications for use	SCARLET® AC-T 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-T cages are intended to be used at one level from the C2-C3 disc to the C7-T1 disc to facilitate intervertebral body fusion with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The SCARLET® AC-T Secured Anterior Cervical Cage is intended to be used as a standalone system used with the two bone screws provided and requires no additional supplementary fixation systems. When used without the two bone screws, SCARLET AC-T cages are to be used with supplemental fixation which has been cleared by the FDA for use in the cervical spine.
Description of the device	The Scarlet® AC-T is a box-shaped spacer with a central cavity that can be filled with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. Scarlet® AC-T is available in convex or lordotic profiles. Scarlet® AC-T comes in two footprints and six heights in order to accommodate different patient anatomies. The Scarlet® AC-T fixation screws are available with diameters 3.0 mm and 3.5 mm and come in various sizes so as to accommodate different patient anatomies. The SCARLET® AC-T spacer and screws are made of Titanium alloy Ti6Al4V ELI conforming to ISO 5832.3 and ASTM F136. SCARLET® AC-T is single-use device provided sterile (gamma radiation) and supplied with dedicated surgical instruments. 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	Added Scarlet® AC-T fixation screws are 3.5 mm in diameter with a core diameter of 2.1 mm for the first-intention screw and 2.6 mm for the revision screw. These added Scarlet® AC-T fixation screws present a modified distal tip to facilitate the insertion into the bone. All other dimensions and features (material, hexalobe imprint, anti-backout mechanism) are identical. As was established in this submission added Scarlet® AC-T fixation screws are substantially equivalent and has the same technological and mechanical characteristics to predicate devices.
Discussion of Testing	No additional testing has been performed for the added Scarlet® AC-T fixation screws. A risk analysis was performed to determine that additional testing was not needed.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the Scarlet® AC-T has demonstrated substantial equivalence to the identified predicate devices.