August 20, 2026

Spineart SA
Estelle Godeau
Regulatory Affairs & Market Access Director
Chem Du Pré-Fleuri 3
1228 Plan-les-Ouates
Switzerland

Re: K261049
Trade/Device Name: SCALA® TL
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 22, 2026
Received: July 22, 2026

Dear Estelle Godeau:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261049

Please provide the device trade name(s).

SCALA® TL

Please provide your Indications for Use below.

The SCALA® TL Posterior Expandable Cage System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L1-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. It is used in patients who have had at least six months of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level(s) may be treated with the device. This device is intended to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and a supplemental spinal fixation system that is cleared for use in the lumbosacral spine.
Additionally, the SCALA® TL Posterior Expandable Cage System can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

510(k) #: K261049

510(k) Summary

Prepared on: 2026-08-19

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	Ms. Estelle Godeau
Applicant Contact Email	elefeuvre@spineart.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SCALA® TL
Common Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification Name	Intervertebral Body Fusion Device
Regulation Number	888.3080
Product Code(s)	MAX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K163364	MOJAVE Expandable Interbody System	MAX
K171633	NuVasive TLX Interbody System	MAX
K192115	SABLE Expandable Spacer	MAX
K153621, K181203	Juliet Ti	MAX

Device Description Summary

21 CFR 807.92(a)(4)

The SCALA® TL Posterior Expandable Cage System has been designed for lumbar discectomy with fusion. It comprises a medical grade titanium alloy (Ti-6Al-4V) components assembly which enables an independent control in height and lordosis to accommodate patient's anatomy variations. The system may be implanted via an open or a minimal invasive posterior or transforaminal approach. The SCALA® TL Posterior Expandable Cage System is available in several heights, lengths and widths.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SCALA® TL Posterior Expandable Cage System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L1-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. It is used in patients who have had at least six months of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level(s) may be treated with the device. This device is intended to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and a supplemental spinal fixation system that is cleared for use in the lumbosacral spine.
Additionally, the SCALA® TL Posterior Expandable Cage System can be used as an adjunct to fusion in patients diagnosed with

degenerative scoliosis.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications are the same.

Technological Comparison 21 CFR 807.92(a)(6)

Based upon the same intended purpose, surgical approach, design, principle of operation, technology, and materials, SCALA® TL Posterior Expandable Cage is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Static and dynamic Axial Compression, Static and dynamic Shear-compression 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 SCALA® TL worst-case specimens dynamically tested.
Expulsion characterization was conducted according to ASTM Draft F-04.25.02.02.

Clinical data were not necessary.

Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the SCALA® TL implants have demonstrated substantial equivalence to the identified predicate devices.