May 1, 2026

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

Re: K253966
Trade/Device Name: PERLA® TL Posterior Thoraco-lumbar Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: December 11, 2025
Received: December 11, 2025

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

COLIN O'NEILL -S

Colin O'Neill, M.B.E.
Acting 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.

510(k) Number *(if known)*
K253966

Device Name
PERLA® TL Posterior Thoraco-lumbar Fixation System

Indications for Use *(Describe)*
The PERLA® TL Posterior Thoraco-lumbar Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• degenerative disc disease;
• spondylolisthesis;
• fracture;
• dislocation;
• scoliosis;
• kyphosis;
• spinal tumor;
• and failed previous fusion (pseudarthrosis).
When used for posterior non-cervical pedicle screw fixation in pediatric patients, the PERLA® TL Posterior Thoraco-lumbar Fixation System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PERLA® TL Posterior Thoraco-lumbar Fixation System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
When used in conjunction with TEKTONA® HV US bone cement system, the PERLA®TL system is intended to restore the integrity of the spinal column even in the absence of fusion for a limited period of time, in patients whom life expectancy is of insufficient duration to permit achievement of fusion in advanced stage of thoracic and lumbar spine tumors. The PERLA®TL 35mm to 60mm lengths Screws augmented used with TEKTONA® HV US bone cement system are intended to be used at spinal levels where the structural integrity is not severely compromised.

TEKTONA® HV US Bone Cement
TEKTONA® HV US Bone Cement is indicated for the treatment of pathological fractures of the vertebral body using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).
When used in conjunction with PERLA®TL system, TEKTONA® HV US Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. PERLA®TL Screws augmented with TEKTONA® HV US Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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."

510(k) #: K253966

510(k) Summary

Prepared on: 2026-04-14

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	PERLA® TL Posterior Thoraco-lumbar Fixation System
Common Name	Thoracolumbosacral pedicle screw system
Classification Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3070
Product Code(s)	NKB, KWP, PML

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193396	PERLA® TL	NKB
K203222	PERLA® TL	NKB
K213470	PERLA® TL	NKB
K231069	PERLA® TL	NKB

Device Description Summary

21 CFR 807.92(a)(4)

The PERLA® TL System consists of a range of screws, rods, set screws, hooks, rod connectors and cross-connectors. These connecting components can be rigidly locked to the rod in a variety of configurations to be adapted for the individual case. The PERLA® TL System is manufactured from medical grade titanium alloy and medical grade cobalt chromium conforming respectively to standards ASTM F136 and ASTM F1537.

The PERLA® TL Posterior Thoraco-lumbar Fixation System implants are delivered sterile (gamma sterilization) and supplied with dedicated surgical instruments (reusable – provided non-sterile except for the drill supplied as sterile or not sterile). Bacterial endotoxin testing as specified in USP standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device.
The subject product line extension of the PERLA® TL Posterior Thoraco-lumbar Fixation System manufactured by Spineart (K193396, K203222, K203506, K213470, K230774, K231069) consists of addition of:
- Screws: Pelvic Screws and Dual Rod Polyaxial Screws
- Rod connectors: Articulated Rod Connectors
- Setscrews: Pelvic Setscrews

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The PERLA® TL Posterior Thoraco-lumbar Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• degenerative disc disease;
• spondylolisthesis;
• fracture;
• dislocation;
• scoliosis;
• kyphosis;
• spinal tumor;
• and failed previous fusion (pseudarthrosis).
When used for posterior non-cervical pedicle screw fixation in pediatric patients, the PERLA® TL Posterior Thoraco-lumbar Fixation System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PERLA® TL Posterior Thoraco-lumbar Fixation System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
When used in conjunction with TEKTONA® HV US bone cement system, the PERLA®TL system is intended to restore the integrity of the spinal column even in the absence of fusion for a limited period of time, in patients whom life expectancy is of insufficient duration to permit achievement of fusion in advanced stage of thoracic and lumbar spine tumors. The PERLA®TL 35mm to 60mm lengths Screws augmented used with TEKTONA® HV US bone cement system are intended to be used at spinal levels where the structural integrity is not severely compromised.

TEKTONA® HV US Bone Cement
TEKTONA® HV US Bone Cement is indicated for the treatment of pathological fractures of the vertebral body using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).
When used in conjunction with PERLA®TL system, TEKTONA® HV US Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. PERLA®TL Screws augmented with TEKTONA® HV US Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject devices have the same intended use and indications for use, as the following PERLA TL predicates:
- K193396, S.E. 12/06/2019
- K203222, S.E. 11/02/2020
- K213470, S.E. 10/28/2021
- K231069, S.E. 04/14/2023

Technological Comparison

21 CFR 807.92(a)(6)

As was established in this submission, the PERLA® TL added components are substantially equivalent and have the same technological characteristics to predicate devices in areas including materials, similar overall design, range of sizes, mechanical performance and sterilization.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

In accordance with the Guidance for Industry and FDA Staff - Spinal System 510(k)'s, Spineart has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices.
The subject devices have been tested or rationalized based on if Spineart believes that testing is not warranted for the subject devices as they do not present a new worst-case when compared to the predicates.
Testing and/or rationales were completed for the following:
- ASTM F1717: Static compression, static torsion, and dynamic compression
- ASTM F1798: Static axial gripping and static axial torsion gripping
- ASTM F2503: MRI compatibility evaluation

For the tested subject devices, the pre-determined acceptance criteria was met for all tests. For subject devices that are rationalized, all existing predicate data previously provided in the predicate 510(k) is still applicable.
Therefore, Spineart believes the design verification testing demonstrated that the subject devices are substancially equivalent to the predicate device.

No clinical testing was required for the subject device.

The data included in this submission demonstrate substantial equivalence to the predicate devices. PERLA® TL System is as safe, as effective, and performs as well as, or better, than the predicate devices.