Spineart SA
Franck Pennesi
Chief Technical Officer
3 Chemin du Pré-Fleuri
Plan-les-Ouates, Geneve 1228
Switzerland

October 25, 2023

Re: K231069
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: September 19, 2023
Received: September 21, 2023

Dear Franck 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 (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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2023.10.25 13:27:19 -04'00'

for

Colin O'Neill, M.B.E.
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)*
K231069

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.

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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**Traditional 510k**
**PERLA® TL Extension Line**

## 510(k) SUMMARY

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| 510k | TRADITIONAL |
| Basis for submission | Extension of the range of PERLA® TL Posterior Thoraco-lumbar Fixation System and MRI update for Spineart PERLA® TL Posterior Thoraco-lumbar Fixation System |
| Submitted by | SPINEART<br>3 Chemin du Pré-Fleuri<br>1228 PLAN LES OUATES<br>GENEVA SWITZERLAND |
| Contacts | Franck PENNESI Chief Technical Officer<br>Phone : +41 22 570 1200 Fax : +41 22 594 8306<br>Mail : fpennesi@spineart.com<br>Regulatory contact : Estelle LEFEUVRE elefeuvre@spineart.com |
| Date Prepared | April 11th, 2023 |
| Common Name | Pedicle screw spinal system |
| Trade Name | PERLA® TL Posterior Thoraco-lumbar Fixation System |
| Classification Name | Thoracolumbosacral pedicle screw system |
| Class | II |
| Product Code | NKB, KWP |
| CFR section | 888.3070 |
| Device panel | ORTHOPEDIC |
| Legally marketed predicate devices | Primary predicate: PERLA® TL Posterior Thoraco-lumbar Fixation System manufactured by Spineart (K193396, K203222)<br>Additional predicates:<br>- ROMEO® 2 Posterior Osteosynthesis System manufactured by Spineart (K172101),<br>- SeaSpine® Daytona® Small Stature Spinal System manufactured by SeaSpine Orthopedics Corporation (K163604, K180686)<br>- SeaSpine Mariner Pedicle Screw System manufactured by SeaSpine Orthopedics Corporation (K173882)<br>- Mariner Outrigger Revision System manufactured by SeaSpine Orthopedics Corporation (K183639) |
| Indications for use | 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. |

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| Description of the device | The PERLA® TL Posterior Thoraco-lumbar Fixation 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 Posterior Thoraco-lumbar Fixation System is manufactured from medical grade titanium alloy and medical grade cobalt chromium conforming respectively to standards ASTM F136 and ASTM F1537.<br>The PERLA® TL Posterior Thoraco-lumbar Fixation System implants are delivered sterile (gamma sterilization) 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 | The subject product line extension of the PERLA® TL Posterior Thoraco-lumbar Fixation System manufactured by Spineart (K193396) consists of addition of<br>- Rod connectors (Parallel Open/Open (W-Shape), Parallel Open/Open (T-Shape), Parallel Open/Close, Parallel Close/Close),<br>- Rods (Z-Rods – pre-bent)<br>As it was established in this submission, the PERLA® TL Posterior Thoraco-lumbar Fixation System added components are substantially equivalent and have the same technological characteristics to predicate devices in areas including indications for use, function, material composition, design, range of sizes and mechanical performance. |

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| Discussion of Testing | **Mechanical testing:**<br>Axial gripping and static torsion testing were conducted in conformance with ASTM F1798 to determine if the range extensions introduce new worst case into the range. Results demonstrate that no new worst case has been added into the range.<br><br>**MRI Safety Evaluation:**<br>In accordance with the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" (Issued May 2021), testing has been completed on the worst case implants. The following testing has been completed and provided a determination that the subject Spineart PERLA® TL Posterior Thoraco-lumbar Fixation System in this 510(k) submission has been determined to be MR conditional:<br>- **ASTM F2052-2021**: *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*<br>- **ASTM F2213-17**: *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*<br>- **ASTM F2119-07**: *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*<br>- **ASTM F2182-19e2**: *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance*<br>- **ASTM F2503-20**:"*Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*" |
| Conclusion | **Mechanical testing:**<br>Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the PERLA® TL Posterior Thoraco-lumbar Fixation System added components have demonstrated substantial equivalence to the identified predicate devices.<br><br>**MRI Safety Evaluation:**<br>The Spineart PERLA® TL Posterior Thoraco-lumbar Fixation System has been labeled as MR Conditional in accordance with **ASTM F2503-20** "*Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*" |