February 5, 2020

Spineart
Franck Pennesi
Chief Technical Officer
3 Chemin du Pre-Fleuri
1228 Plan Les Ouates
Geneva Switzerland

Re: K193396
Trade/Device Name: PERLA® TL posterior osteosynthesis system
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: December 3, 2019
Received: December 6, 2019

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 (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/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 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 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,

for

Ronald P. Jean, Ph.D.
Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193396

Device Name
PERLA® TL posterior osteosynthesis system

Indications for Use *(Describe)*
The PERLA® TL posterior osteosynthesis 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 osteosynthesis system is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis.
The PERLA® TL posterior osteosynthesis 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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510(k) SUMMARY

510k	TRADITIONAL
Basis for submission	New devices
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 5, 2020
Common Name	Pedicle screw spinal system
Trade Name	PERLA® TL posterior osteosynthesis 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: ROMEO® 2 Posterior Osteosynthesis System manufactured by Spineart (K172101) Additional predicate: Mariner Outrigger Revision System manufactured by SeaSpine Orthopedics Corp. (K183639); Reform® Midline Cortical Screw System manufactured by Precision Spine, Inc (K173130); Reform Pedicle Screw System manufactured by Precision Spine, Inc (K151422)
Indications for use	The PERLA® TL posterior osteosynthesis 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 osteosynthesis system is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PERLA® TL posterior osteosynthesis system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach

Description of the device	The PERLA® TL posterior osteosynthesis 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 osteosynthesis implants are delivered either non sterile or 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.
Technological characteristics compared to the predicate devices	As was established in this submission, the PERLA® TL posterior osteosynthesis system is substantially equivalent and has the same technological characteristics to its predicate devices in areas including indications for use, function, material composition, design, range of sizes and mechanical performance.
Discussion of Testing	The following non-clinical tests were conducted on the PERLA® TL posterior osteosynthesis system: Static Axial Gripping per ASTM F1798, Static Axial torque gripping per ASTM F1798, Static Compression bending per ASTM F1717, Static Torsion per ASTM F1717 and Dynamic Compression bending per ASTM F1717. Results demonstrate comparable mechanical properties to the predicate device ROMEO® 2 Posterior Osteosynthesis System manufactured by Spineart (K172101). Additionally, a cadaver lab trial was conducted.
Conclusion	Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the PERLA® TL posterior osteosynthesis system has demonstrated substantial equivalence to the identified predicate devices.