February 25, 2019

SPINEART
Mr. Franck Pennesi
Chief Technical Officer
3 Chemin du Pré Fleuri
1228 Plan Les Ouates
Geneva, Switzerland

Re: K190071
Trade/Device Name: Perla® Posterior Cervico-Thoracic Fixation System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: January 11, 2019
Received: January 15, 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,

Ronald P. Jean -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)*
K190071

Device Name
Perla® Posterior Cervico-Thoracic Fixation system

Indications for Use *(Describe)*
The PERLA® posterior cervico-thoracic fixation system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C 1 to C7) and the thoracic spine from Tl-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The PERLA® posterior cervico-thoracic fixation system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the PERLA® posterior cervico-thoracic fixation system may be connected to the ROMEO® Posterior Osteosynthesis System with rod connectors. Transition rods may also be used to connect the PERLA® posterior cervico-thoracic fixation system to the ROMEO® Posterior Osteosynthesis System. Refer to the ROMEO® Posterior Osteosynthesis System package insert for a list of the ROMEO® Posterior Osteosynthesis System indications of use.

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
PERLA® POSTERIOR CERVICO-THORACIC FIXATION SYSTEM

510(k) SUMMARY

Type of 510k	510k SPECIAL – DEVICE MODIFICATION
Reason for submission	Extension of the range of Perla® Posterior Cervico-Thoracic Fixation system
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 20, 2019
Common Name	Orthosis, Cervical Pedicle Screw Spinal Fixation
Trade Name	Perla® Posterior Cervico-Thoracic Fixation system
Product Code	NKG / KWP
Class	Unclassified
Device panel	Orthopedic
Legally marketed predicate devices	Primary predicate: PERLA Posterior Cervico-Thoracic Fixation System (K153386) manufactured by Spineart Additional predicate: None
Indications for use	The PERLA® posterior cervico-thoracic fixation system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C 1 to C7) and the thoracic spine from Tl-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The PERLA® posterior cervico-thoracic fixation system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the PERLA® posterior cervico-thoracic fixation system may be connected to the ROMEO® Posterior Osteosynthesis System with rod connectors. Transition rods may also be used to connect the PERLA® posterior cervico-thoracic fixation system to the ROMEO® Posterior Osteosynthesis System. Refer to the ROMEO® Posterior Osteosynthesis System package insert for a list of the ROMEO® Posterior Osteosynthesis System indications of use.

Description of the device	The Spineart Perla® system is a posterior cervico-thoracic fixation system intended to provide stabilization to promote fusion of the cervical spine and the upper thoracic spine. Perla® system consists of a variety of shapes and sizes of rods, hooks, multi-axial screws, set screws, rod connectors and transverse connectors. These connecting components can be rigidly locked to the rod in a variety of configurations to be adapted for the individual case. The multi-axial screws are available with diameters 3.5mm and 4.0 mm with lengths ranging from 08 mm up to 52 mm. The purpose of this Special 510(k) application is to introduce an additional range of multi-axial screw with 4.5 mm diameter and lengths ranging from 08 mm up to 52 mm to the Perla® spinal system.
Technological characteristics compared to the predicate devices	The unique aspect of the new 4.5 mm multi-axial screws which differs from the existing Perla® multi-axial screws is the diameter of the bone screw that is enlarged to diameter 4.5 mm. All other design features are strictly the same as for existing Perla® multi-axial screws. Compared with previously cleared predicate multi-axial screws, the subject multi-axial screws with 4.5 mm in diameter are made of the same material (Titanium alloy Ti6Al4V ELI conforming to ASTM F136), available in the same lengths ranging from 08 mm up to 52 mm, present the same design and polyaxiality of 60° and use the same set screw. Both previously cleared and new multi-axial screws are delivered sterile (gamma sterilization) and supplied with the same dedicated surgical instruments (reusable – provided non-sterile). The following non-clinical tests were conducted on predicate devices: - Static Compression Bending, Static Torsion and Dynamic Compression Bending according to ASTM F1717 - Static flexion-extension testing, Static axial gripping and Static torsion gripping according to ASTM F1798 - Axial pullout strength and Torque to failure according to ASTM F543 Bacterial endotoxin testing as specified in USP standard is used for pyrogenicity testing to achieve the Endotoxin limit of 20 EU / device.
Discussion of Testing	An engineering analysis was performed and determined the new 4.5 mm multi-axial screws do not constitute a new worst-case design in the Perla spinal system. No additional testing has been performed for the Perla® 4.5 mm multi-axial screws.
Conclusion	Based on the design features, technological characteristics, feature comparisons, and indications for use, the Perla® 4.5 mm multi-axial screws have demonstrated substantial equivalence to the identified predicate devices.