



Food and Drug Administration  
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SPINEART

January 25, 2016

Mr. Franck Pennesi  
Director of Industry & Quality  
International Center Cointrin  
20 route de pré-bois – CP 1813  
1215 Geneva 15  
SWITZERLAND

Re: K153386

Trade/Device Name: PERLA® Posterior Cervico-Thoracic Fixation System

Regulatory Class: Unclassified

Product Code: NKG, KWP

Dated: November 19, 2015

Received: November 23, 2015

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K153386

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 T1-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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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TRADITIONAL 510k  
PERLA® POSTERIOR CERVICO-THORACIC FIXATION SYSTEM



510(k) SUMMARY

Submitted by	<p><b>SPINEART</b> International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND</p>
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Date Prepared	January 14 <sup>th</sup> 2016
Trade Name	PERLA® Posterior Cervico-Thoracic Fixation System
Common Name	Orthosis, Cervical Pedicle Screw Spinal Fixation Posterior Cervico-Thoracic Fixation system
Classification Name	Appliance, Fixation, Spinal Interlaminar
Product Code / Class CFR section	<p>Primary: NKG, Unclassified CFR Section: Unclassified Subsequent: KWP, Class II CFR Section: 888.3050 Spinal Interlaminar fixation orthosis</p>
Device panel	Orthopedic
Legally marketed predicate devices	<p><u>Primary predicate</u>: Vertex Reconstruction System (K143471) manufactured by Medtronic Sofamor Danek USA, Inc <u>Reference devices</u>: Vertex Reconstruction System (K003780) manufactured by Medtronic Sofamor Danek, Inc Synthes Cervifix/Axon (K023675) manufactured by Synthes (USA); Synthes Cervifix System (K991089) manufactured by Synthes Spine; Mountaineer OCT Spinal System (K110353) manufactured by Depuy Spine, Inc</p>
Indications for use	<p>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 T1-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.</p> <p>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.</p>

	<p>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.</p>
Description of the device	<p>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 Perla® system can also be linked to the cleared Spineart Romeo®2 spinal system (K151695) using the specific Perla® Axial and Parallel Rod to Rod connectors 3.5/5.4mm or the Perla® Transition Rods 3.5/5.4mm which are part of this submission</p>
Technological Characteristics	<p>The multi-axial screws are available with diameters 3.5mm and 4.0mm with lengths ranging from 8 mm up to 52mm.</p> <p>The 3.5mm diameter rods come in various lengths and have straight or pre-bent designs. The Perla® system comprises also transition rods with dual diameters of 3.5/5.4mm, a range of hooks and connectors.</p> <p>The implantable components of the PERLA® posterior cervico-thoracic fixation system are made of medical grade titanium alloy and cobalt chromium conforming to standards ASTM F136 and F1537, respectively.</p> <p>The implantable components of the PERLA® posterior cervico-thoracic fixation system are delivered sterile (gamma sterilization).</p> <p>The PERLA® posterior cervico-thoracic fixation system is supplied with all the surgical instruments required for its installation.</p>
Performance Data	<p>Published literature and bench testing per ASTM F1717 demonstrate that the PERLA® posterior cervico-thoracic fixation system is substantially equivalent to the predicate devices.</p> <p>The following non-clinical tests were conducted:</p> <ul style="list-style-type: none"> <li>✓ Static Compression Bending, Static Torsion and Dynamic Compression Bending according to ASTM F1717</li> <li>✓ Static flexion-extension testing, Static axial gripping and Static torsion gripping according to ASTM F1798</li> <li>✓ Axial pullout strength and Torque to failure according to ASTM F543</li> </ul>
Conclusion	<p>Design comparisons and non-clinical performance testing demonstrate that the PERLA® posterior cervico-thoracic fixation system is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function.</p>