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

Re: K172101
Trade/Device Name: ROMEO® 2 Posterior Osteosynthesis System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: July 10, 2017
Received: July 12, 2017

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 Part 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 (DICE) 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 (DICE) at its toll-free number (800) 638-2041 or
(301) 796-7100 or at its Internet address

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
Indications for Use

The ROMEO® 2 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 ROMEO® 2 Posterior Osteosynthesis System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The ROMEO® 2 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)

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## 510(k) SUMMARY

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<th><strong>510k</strong></th>
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<tr>
<td><strong>Basis for submission</strong></td>
<td>The purpose of this submission is to make modifications to the indications for use, to add additional sizes and a new connector design to the ROMEO® 2 Posterior Osteosynthesis System cleared under K081165, K093170, K093936, K101678, K111127, K112108, K130267, K140948 and K151695</td>
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| **Submitted by** | SPINEART  
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Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr |
| **Date Prepared** | Revised September 8, 2017 |
| **Common Name** | Pedicle screw spinal system |
| **Trade Name** | ROMEO® 2 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 (Ellipse) Posterior Osteosynthesis System (K081165) manufactured by Spineart  
Additional predicates: ROMEO Posterior Osteosynthesis System (K093170, K093936, K101678, K111127, K112108, K130267, K140948, K151695) manufactured by Spineart, Reform Pedicle Screw System (K143248) manufactured by Precision Spine, Inc and Xia (K142381) / Xia - Mantis (K133188) manufactured by Stryker Spine |
| **Indications for use** | The ROMEO®2 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 ROMEO®2 Posterior Osteosynthesis System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The ROMEO®2 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 ROMEO®2 Posterior Osteosynthesis System comprises polyaxial screws, monoaxial screws, spondylolisthesis screws, setscrew, straight and pre-bent Titanium or CoCr rods, and various connectors available in several sizes and models to accommodate different patient anatomies. ROMEO® implantable components are single-use device provided sterile (gamma radiation) and supplied with dedicated surgical instruments. |
| Technological characteristics compared to the predicate devices | The line extension to the ROMEO®2 Posterior Osteosynthesis System include additional lengths of polyaxial Screws, additional lengths and diameters of spondylolisthesis screws and addition of a new design of open iliac Connector. As was established in this submission through a side by side comparison, previously cleared and added components included in the ROMEO® Posterior Osteosynthesis System 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. |
| Discussion of Testing | The following non-clinical tests were conducted to demonstrate that the open iliac Connector is substantially equivalent to its predicate device: Axial Rotation (rotation around the rod) and Axial Push Down (slipping along the rod) tests per ASTM F1798. Results demonstrate comparable mechanical properties to the predicate devices. It has been demonstrated that the ROMEO®2 Screw Line Extension range does not introduce new worst-case design and remains substantially equivalent to the predicate devices. |
| Conclusion | Based on the design features, technological characteristics, feature comparisons, indications for use, and non-clinical performance testing, the ROMEO®2 Posterior Osteosynthesis System has demonstrated substantial equivalence to the identified predicate devices. |