DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 10, 2015

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

Re: K151695
Trade/Device Name: Romeo® posterior osteosynthesis system
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: June 22, 2015
Received: June 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 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151695

Device Name
Romeo® posterior osteosynthesis system

Indications for Use *(Describe)*
Romeo® 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: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).
When used as a posterior, non-cervical, non-pedicle screw fixation system, Romeo® posterior osteosynthesis system is intended for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TRADITIONAL 510k

ROMEO® Posterior Osteosynthesis System

510(k) SUMMARY

Submitted by	**SPINEART** International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 570 1246 Fax : +41 22 799 40 26 Mail : fpennesi@spineart.com Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) Mail : idrubaix@nordnet.fr
Date Prepared	August 17th 2015
Common Name	Pedicle screw spinal system
Trade Name	Romeo® posterior osteosynthesis system
Classification Name	Pedicle screw spinal system
Class	II
Product Code	MNH, MNI
CFR section	888.3070
Device panel	ORTHOPEDIC
Legally marketed predicate devices	Primary predicate: Ellipse posterior osteosynthesis system (K081165) manufactured by Spineart Other predicate: Romeo® posterior osteosynthesis system (K111127, K141835) manufactured by Spineart
Indications for use	Romeo® 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: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). When used as a posterior, non-cervical, non-pedicle screw fixation system, Romeo® posterior osteosynthesis system is intended for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Description of the device	The Romeo® posterior fixation system comprises polyaxial screws, monoaxial screws, spondylolisthesis screws, setscrew, straight and pre-bent Titanium or CoCr rods, and various connectors. The Romeo® screws come in various lengths (from 25 to 90 mm) and diameters (4.0, 4.5, 5.0, 5.5, 6.0, 7.0 and 8.0 mm) to accommodate different patient anatomies. Romeo® components are delivered sterile (gamma sterilization) in a dedicated packaging or not sterile upon request. The Romeo® posterior fixation system is supplied with a set of surgical instruments.
Technological Characteristics	The purpose of this 510(k) submission is to obtain clearance for a Romeo® Setscrew with a modified hexalobe imprint, a Romeo® Parallel Rod Connector and a T Rod Connector. These Romeo® components are made of Titanium alloy Ti6Al4V ELI conforming to ISO 5832.3 and ASTM F136 and are fully compatible with components of the existing Romeo® posterior fixation system.
Discussion of Testing	The following non-clinical tests were conducted: Torsion test for the set-screw according to in-house protocol; Axial Push Down and Axial Torsion in subassembly according to ASTM F1798 for the connectors. Results demonstrate comparable mechanical properties to the predicate devices.
Conclusion	Design comparisons and non-clinical performance testing demonstrate that the added devices (Setscrew, T connector and Parallel Rod Connector O/O) are substantially equivalent to their predicate devices (K081165, K111127 and K141835) in terms of intended use, material, design, mechanical properties and function.