510(k) SUMMARY

MAY 2 0 2014

Submitted by	**SPINEART** International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
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Date Prepared	April 9th 2014
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	Ellipse posterior osteosynthesis system (K081165) and Romeo® posterior osteosynthesis system (K101678)
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 CoCrMo rods, and cross connectors. The Romeo® Polyaxial 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. The modification to Romeo® posterior osteosynthesis system consists of the addition of a polyaxial pedicle screw 5 mm in diameter and 25 mm in length.
Technological Characteristics	Romeo® pedicle screws are made of Titanium Ta6V Eli grade conforming to ASTM F136. Romeo® pedicle screws are delivered either sterile (gamma sterilization) or not sterile and supplied with dedicated surgical instruments (reusable – provided non sterile).
Discussion of Testing	Romeo® posterior osteosynthesis system conforms to special control established for Pedicle screw spinal system and to « Spinal System 510(k)s - Guidance for Industry and FDA Staff Document » issued on: May 3, 2004. No additional testing has been performed for the added polyaxial pedicle screw.
Conclusion	The extended range of Romeo® posterior osteosynthesis system is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function. Verification Activity and Validation Activity demonstrate that the added polyaxial pedicle screw is as safe, as effective, and performs at least as safely and effectively as its predicates polyaxial pedicle screws (K081165 & K101678).

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

May 20, 2014

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

Re: K140948
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: April 22, 2014
Received: April 25, 2014

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140948

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)

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)*

James P. Bertram -S
2014.05.19 14:42:28 -04'00'

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