



Food and Drug Administration
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August 4, 2016

Spineway S.A.
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

Re: K161387

Trade/Device Name: Mont Blanc and Mont Blanc MIS Spinal Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP
Dated: June 3, 2016
Received: June 6, 2016

Dear Dr. Jansen:

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,

Lori A. Wiggins -S

for

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)
K161387

Device Name
Mont Blanc and Mont Blanc MIS Spinal Systems

Indications for Use (Describe)

The Mont Blanc and Mont Blanc MIS Spinal Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine and sacral/iliac screw fixation.

The Mont Blanc and Mont Blanc MIS Spinal Systems are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (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 in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the Mont Blanc MIS System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (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 in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Mont Blanc and Mont Blanc MIS Spinal Systems metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Mont Blanc and Mont Blanc MIS Spinal Systems are 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared: August 2, 2016

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Trade Name: Mont Blanc and Mont Blanc MIS Spinal Systems
Product Class: Class III
Classification: 888.3070 Pedicle Screw Spinal System
Common Name: Pedicle Screw System
Product Codes: NKB, MNI, MNH, KWP, OSH
Panel Code: 87

Indications for Use:

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Purpose of Submission:

The additional components subject of this new file are part of the Mont Blanc and Mont Blanc MIS Spinal Systems and consists of Ø5.5mm pre-bent and straight bullet shaped titanium rods as well as Cobalt-chrome straight rods.

Device Description:

The Spineway Mont Blanc and Mont Blanc MIS Spinal Systems are composed of implant device made from a titanium alloy Ti6Al4V-ELI per ISO 5832-3 and Cobalt-Chrome per ISO 5832-12. All implant components are provided sterile. It is to be implanted from the posterior approach. The screws are available as monobloc and monobloc reduction (traction) screws and polyaxial and polyaxial reduction (traction) screws in diameters from 4.0-8.0 mm and in lengths from 25-55 mm and polyaxial iliac screws of 7 and 8mm diameters with lengths from 55mm to 110mm. Rods are available in 5.5mm diameter in lengths from 40-500 mm. Hooks are available in various sizes to attach to the thoracic and lumbar spine. Transverse connectors are available in various sizes to attach to the two parallel rods. Associated instrumentation to complete the procedure is provided.

Screws for MIS applications are available as polyaxial cannulated screws in diameter from 4.5-8mm and in lengths from 25-60mm. Rods for MIS applications are available as 5.5mm pre-bent rods from 50-140mm and straight rods from 50-500mm.

Predicate Device(s):

The Spineway Mont Blanc and Mont Blanc MIS Spinal Systems are substantially equivalent to the primary predicate, the DePuy Viper and Viper2 Systems (K131802). The additional predicate device is the Spineway Mont Blanc system (K150185).

Performance Standards:

The pre-clinical testing performed per ASTM F1717-14 includes:

- Static compression bend
- Static torsion
- Dynamic compression bend

Pre-clinical testing performed per ASTM F1798-98 (2003), which includes:

- Axial gripping capacity
- Torsional gripping capacity
- Flexural gripping capacity

Bacterial endotoxin testing per USP34 and NF 29. Material-mediated pyrogenicity per ISO 10993-11 (2006) and ASTM F750-87 (2007).

Conclusion:

Spineway concludes that the Spineway Mont Blanc and Mont Blanc MIS Spinal Systems are substantially equivalent to the predicate devices in regard to indications for use, materials, function, sizes and mechanical test results and raises no new questions of safety or effectiveness.