September 12, 2019

Spineway SA
% Tamala J. Wampler
Regulatory and Quality Consultant
Novus Management Group LLC
6686 Dimmick Road
West Chester, Ohio 45069

Re: K191726
Trade/Device Name: mont blanc & mont blanc MIS Spinal Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: May 3, 2019
Received: June 27, 2019

Dear Ms. Wampler:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191726

Device Name
mont blanc spinal system

Indications for Use *(Describe)*
The mont blanc system is 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/iliac spine.

This mont blanc system is intended for posterior noncervical pedicle fixation and non-pedicle fixation (from T1 to S1) for the following indications in skeletally mature patients:

• 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;
• deformities (i.e., scoliosis, kyphosis, and/or lordosis);
• spinal tumor,
• pseudoarthrosis; and
• failed previous fusion.

The mont blanc system is intended to be used with autograft and/or allograft.

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.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191726

Device Name
mont blanc MIS spinal system

Indications for Use *(Describe)*
The mont blanc MIS system is 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.

This mont blanc MIS system is intended for posterior noncervical pedicle fixation and non-pedicle fixation (from T1 to S1) utilizing a percutaneous minimally approach for the following indications in skeletally mature patients:

• 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;
• deformities (i.e., scoliosis, kyphosis, and/or lordosis);
• spinal tumor,
• pseudoarthrosis; and
• failed previous fusion.

The mont blanc MIS system is intended to be used with autograft and/or allograft.

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)*

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510(k) Summary

Submitter's Name:	Spineway SA
Submitter's Address:	7 Allee Moulin Berger 69130 Ecully Rhone-Alpes, FRANCE
Submitter's Telephone:	(513) 593-4944
Company Contact Person:	Héloïse MACAIRE Regulatory Affairs Specialist
Contact Person:	Tamala J. Wampler Novus Management Group LLC. 513-593-4944
Date Summary was Prepared:	10/14/2018
Trade or Proprietary Name:	mont blanc & mont blanc MIS Spinal Systems
Common or Usual Name:	Thoracolumbosacral pedicle screw system
Classification:	Class II per 21 CFR §888.3070
Product Code:	NKB, KWP
Classification Panel:	Division of Orthopedic Devices
Panel Code:	87

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Spineway mont blanc & mont blanc MIS Spinal Systems are implant device systems comprised of a titanium alloy Ti 6Al-4V ELI per ISO 5832-3 and Cobalt-Chrome per ISO 5832-12. The fenestrated screws are polyaxial screws in diameters from 5.0 – 8.0 mm and in lengths from 30 – 55 mm. 6 fenestration holes are present in screws of length 35 mm or longer, 3 fenestration holes are present in screws of length 30 mm.

Dual connectors and domino connectors are available to connect 2 parallel rods together, Iliac lateral connectors are available to create an Iliac fixation, and Axial connectors are available to connect 2 coaxial rods together.

Associated instrumentation to complete the procedure is provided reusable and non-sterile.

INDICATIONS FOR USE MONT BLANC SYSTEM

The mont blanc system is 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/iliac spine.

The mont blanc system is intended for posterior noncervical pedicle fixation and non-pedicle fixation (from T1 to S1) for the following indications in skeletally mature patients:

- 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;
- deformities (i.e., scoliosis, kyphosis, and/or lordosis);
- spinal tumor,
- pseudoarthrosis; and
- failed previous fusion.

The mont blanc system is intended to be used with autograft and/or allograft.

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.

INDICATIONS FOR USE MONT BLANC MIS SYSTEM

The mont blanc MIS system is 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.

The mont blanc MIS system is intended for posterior noncervical pedicle fixation and non-pedicle fixation (from T1 to S1) utilizing a minimally approach for the following indications in skeletally mature patients:

- 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;
- deformities (i.e., scoliosis, kyphosis, and/or lordosis);
- spinal tumor,
- pseudoarthrosis; and
- failed previous fusion.

The mont blanc MIS system is intended to be used with autograft and/or allograft.

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.

PREDICATES

mont blanc & mont blanc MIS Spinal Systems are substantially equivalent to the mont blanc & mont blanc MIS Spinal Systems (K161387). mont blanc & mont blanc MIS are provided sterile as was cleared in mont blanc & mont blanc Spinal System (K161387). The mont blanc & mont blanc MIS Spinal Systems also includes bullet shaped rods, pre-bent rods and cobalt-chrome rods cleared in mont blanc Spinal System (K161387). The subject and predicate devices have identical technological characteristics. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use (identical to Primary)
- Materials of manufacture (identical to Primary and Secondary's)
- Structural support mechanism (identical to Primary and Secondary's)

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Type
K161387	mont blanc & mont blanc MIS Spinal Systems	Spineway	Primary
K131802	EXPEDIUM® Spine System, VIPER and VIPER2 Systems	Medos International Sarl	Secondary
K071373	Stryker Spine Xia® III Spinal System	Stryker Spine	Secondary

PERFORMANCE TESTING

Spineway's mont blanc & mont blanc MIS Spinal Systems were evaluated to demonstrate equivalence to the predicate devices. After engineering evaluation of worst-case constructs comprised of Screws, Rods, Locking Screws, & Connectors mechanical testing was performed on the new worst-case constructs. Static Compression Bending, Static Torsion, Torque to Failure and Dynamic Compression Bending per ASTM F1717-15 has been performed to demonstrate substantial equivalence.

The result showed that the worst-case constructs were substantially equivalent to legally marketed devices. No clinical or animal studies were performed.

CONCLUSION

Spineway concludes that the mont blanc & mont blanc MIS Spinal Systems expanded equipment is substantially equivalent to their already marketed configurations in regard to indications for use, materials, function, sizes and mechanical test results and can therefore be added to the mont blanc & mont blanc MIS Spinal Systems without new questions of safety or effectiveness.