



Food and Drug Administration
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September 3, 2015

DePuy Spine, Incorporated
Ms. Laura Bleyendaal
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K151885
Trade/Device Name: SUMMIT[®] SI OCT Spinal Fixation System,
MOUNTAINEER[®] OCT Spinal System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: July 8, 2015
Received: July 9, 2015

Dear Ms. Bleyendaal:

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.

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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,

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)

K151885

Device Name

SUMMIT® SI OCT Spinal Fixation System and MOUNTAINEER® OCT Spinal System

Indications for Use (Describe)

The SUMMIT® SI OCT Spinal Fixation System and MOUNTAINEER® OCT Spinal System are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3):

- traumatic spinal fractures and/or traumatic dislocations;
- instability or deformity;
- failed previous fusions (e.g. pseudarthrosis);
- tumors involving the cervical/thoracic spine;
- and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and
- degenerative disease of the facets with instability.

The SUMMIT and MOUNTAINEER Systems are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The SONGER® Wire/Cable System to be used with the SUMMIT and MOUNTAINEER Systems allows for wire/cable attachment to the posterior cervical spine.

The SUMMIT and MOUNTAINEER Systems can also be linked to the ISOLA®, MONARCH®, MOSS® MIAMI, VIPER® and EXPEDIUM® Spine Systems using the dual wedding band and axial connectors, and via dual diameter rods.

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

A. Submitter Information

510(k) Sponsor: DePuy Spine, Inc.
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Raynham, MA 02767

Contact Person: Laura Bleyendaal
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B. Date Prepared August 10, 2015

C. Device Name

Trade/Proprietary Name: SUMMIT[®] SI OCT Spinal Fixation System
MOUNTAINEER[®] OCT Spinal System

Common/Usual Name: Orthosis, cervical pedicle screw spinal fixation

Device Classification and Regulation: Unclassified pre-amendment device

Classification Product and Panel Code: NKG; Orthopedic; Unclassified
KWP; Orthopedic; 21 CFR 888.3050

D. Predicate Device Name

Primary Predicate Device: Synapse Occipital-Cervical-Thoracic (OCT) System (K142838)

Reference Devices: MOUNTAINEER[®] OCT Spinal System (most recently cleared in K132332)
SUMMIT[®] SI OCT Spinal Fixation System (most recently cleared in K042508)

E. Device Description

The SUMMIT and MOUNTAINEER Systems are posterior spinal fixation systems intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3). The systems are composed of multiple components to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. The systems consist of bone anchors including hooks, SONGER[®] cables and screws, longitudinal members including rods and occipital plates, transverse connectors including cross connectors and interconnection mechanisms including lateral offset connectors, cable connectors, set screws, nuts, axial and wedding band connectors. The system components are implanted using class I exempt manual surgical instruments. This premarket notification expands the indications for use of the SUMMIT and MOUNTAINEER Systems to include posterior cervical screw fixation.

F. Indications for Use

The SUMMIT[®] SI OCT Spinal Fixation System and MOUNTAINEER[®] OCT Spinal System are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3):

- traumatic spinal fractures and/or traumatic dislocations;
- instability or deformity;
- failed previous fusions (e.g. pseudarthrosis);
- tumors involving the cervical/thoracic spine;
- and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and
- degenerative disease of the facets with instability.

The SUMMIT and MOUNTAINEER Systems are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The SONGER[®] Wire/Cable System to be used with the SUMMIT and MOUNTAINEER Systems allows for wire/cable attachment to the posterior cervical spine.

The SUMMIT and MOUNTAINEER Systems can also be linked to the ISOLA[®], MONARCH[®], MOSS[®] MIAMI, VIPER[®] and EXPEDIUM[®] Spine Systems using the dual wedding band and axial connectors, and via dual diameter rods.

G. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

Like the predicate device, the SUMMIT and MOUNTAINEER Systems are designed to achieve immobilization and stabilization as an adjunct to fusion using cervical screw fixation. The technological characteristics, including material (titanium alloy) and design, of the SUMMIT and MOUNTAINEER Systems are similar to those of the predicate device.

H. Materials

The SUMMIT and MOUNTAINEER System components are manufactured from titanium alloy which is anodized. The MOUNTAINEER rods are also available in cobalt-chromium-molybdenum alloy.

I. Performance Data

Published literature and performance testing per ASTM F1717 and ASTM F1798 demonstrate that the SUMMIT and MOUNTAINEER Systems are substantially equivalent to the predicate device.

J. Conclusion

Published literature and performance testing demonstrate that the SUMMIT and MOUNTAINEER Systems are substantially equivalent to the predicate device.