DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Medos International SARL
% Ms. Sheree Geller
Regulatory Affairs Specialist
DePuy Synthes Spine
325 Paramount Drive
Raynham, Massachusetts 02767

July 20, 2017

Re: K171439
Trade/Device Name: EAGLE Plus Anterior Cervical Plate System, EAGLE Plus Micro Anterior Cervical Plate System, PULSE Anterior Cervical Plate System, SKYLINE Anterior Cervical Plate System, SLIM LOC Anterior Cervical Plate System, SWIFT Plus Anterior Cervical Plate System, UNIPLATE Anterior Cervical Plate System, UNIPLATE 2 Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 15, 2017
Received: May 16, 2017

Dear Ms. Geller:

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,

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)*
K171439

Device Name
EAGLE Plus Anterior Cervical Plate System, EAGLE Plus Micro Anterior Cervical Plate System, PULSE Anterior Cervical Plate System, SKYLINE Anterior Cervical Plate System, SLIM LOC Anterior Cervical Plate System, SWIFT Plus Anterior Cervical Plate System, UNIPLATE Anterior Cervical Plate System, UNIPLATE 2 Anterior Cervical Plate System

Indications for Use *(Describe)*
The SLIM LOC Anterior Cervical Plate System and SKYLINE Anterior Cervical Plate System are indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

The EAGLE Plus Anterior Cervical Plate System, EAGLE Plus Micro Anterior Cervical Plate System, SWIFT Plus Anterior Cervical Plate System, UNIPLATE Anterior Cervical Plate System, and UNIPLATE 2 Anterior Cervical Plate System are intended for anterior cervical intervertebral body fixation. These systems are indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indications include symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), re-operation for failed fusion, or instability following surgery for the above indications.

The UNIPLATE and UNIPLATE 2 Anterior Cervical Plate Systems and the EAGLE Plus Micro Anterior Cervical Plate System are also indicated for treatment of spinal stenosis.

The PULSE Anterior Cervical Plate System is indicated for stabilization of the cervical spine from C2 to T1 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

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

Submitter: DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

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Chemin-Blanc 38
2400 Le Locle, Switzerland

Contact Person: Catherine Kilshaw
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Date Prepared: July 18, 2017

Trade Name: SWIFT Plus Anterior Cervical Plate System
EAGLE Plus Anterior Cervical Plate System
EAGLE Plus Micro Anterior Cervical Plate System
PULSE Anterior Cervical Plate System
SKYLINE Anterior Cervical Plate System
SLIM LOC Anterior Cervical Plate System
UNIPLATE Anterior Cervical Plate System
UNIPLATE 2 Anterior Cervical Plate System

Device Class: II

Product Code: KWQ

Common Name: Appliance, Fixation, Spinal Intervertebral Body

Classification Name: Spinal intervertebral body fixation orthosis

Regulation Number: 21 CFR 888.3060

Primary Predicate: SWIFT Plus Anterior Cervical Plate System (K072546)

Additional Predicate Devices:
EAGLE Plus Anterior Cervical Plates (K070994)
EAGLE Plus Micro Anterior Cervical Plate System (K080191)
PULSE Anterior Cervical Plate System (K112724)
SKYLINE Anterior Cervical Plate System (K052552, K103491)
SLIM LOC Anterior Cervical Plate System (K013877)
UNIPLATE Anterior Cervical Plate System (K042544)
UNIPLATE 2 Anterior Cervical Plate System (K082273, K100070)

Submission Purpose: Obtain clearance for MR Conditional Labeling for the systems listed.

Device Descriptions:

SWIFT Plus The SWIFT™ Plus Anterior Cervical Plate System is manufactured from titanium alloy and consists of segmented plates that allow up to 2mm of controlled graft settling between each of the segments. The plates are available with two to six screw hole pairs, in various lengths and two configurations, discectomy and corpectomy. The screws are available in various sizes and screw-tip geometries. A graft screw is available for use in the corpectomy plates and can be used in the SWIFT Plus system.

EAGLE Plus The EAGLE™ Plus Anterior Cervical Plate System consists of an assortment of titanium alloy plates and screws. The plates are available with two to six screw hole pairs in various lengths. The screws are available in various sizes and screw-tip geometries.

EAGLE Micro The EAGLE Plus Micro Anterior Cervical Plate System is designed for use alone or adjacent to a previously implanted anterior cervical plate. The EAGLE Plus Micro Anterior Cervical Plate System consists of an assortment of titanium alloy single-level plates and uses EAGLE Plus screws. The anterior cervical plates are available in various lengths to accommodate varying patient anatomy.

PULSE The DePuy PULSE™ Anterior Cervical Plate System consists of an assortment of titanium alloy plates and screws. The plates have two to four screw-hole pairs in various lengths. The screws are available in

various sizes and screw-tip geometries, including self drilling and blunt tip to create a semi-constrained construct.

SKYLINE The SKYLINE® Anterior Cervical Plate System consists of an assortment of titanium alloy plates and screws. The plates have two to six screw hole pairs in various lengths. The screws are available in various sizes and screw-tip geometries. Both constrained and variable screws are available to create a constrained, variable or hybrid configuration.

SLIM LOC The SLIM LOC® Anterior Cervical Plate System consists of an assortment of titanium alloy plates and screws. The plates are available in lengths ranging from 22-111mm in configurations with 2, 3, 4, 5 or 6 pairs of screw holes. The SLIMLOC screws are available in 4.5mm in diameter and are available as self-drilling in even length sizes ranging from 10-18mm or self-tapping in even length sizes ranging from 10-26mm. Larger diameter screws (4.8mm) are available in 12, 14, and 16mm lengths.

UNIPLATE Anterior UNIPLATE 2 The UNIPLATE® and UNIPLATE® 2 Anterior Cervical Plate Systems consist of an assortment of titanium alloy plates and screws. The anterior cervical plates are available in various lengths to accommodate one to two segments of fixation. The screws are available in various sizes and tip geometries.

Indications: The SLIM LOC Anterior Cervical Plate System and SKYLINE Anterior Cervical Plate System are indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include: instability caused by trauma; instability associated with correction of cervical lordosis and kyphosis deformity; instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery; instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine; instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

The EAGLE Plus Anterior Cervical Plate System, EAGLE Plus Micro Anterior Cervical Plate System, SWIFT Plus Anterior Cervical Plate System, UNIPLATE Anterior Cervical Plate System, and UNIPLATE 2 Anterior Cervical Plate System are intended for anterior cervical intervertebral body fixation. These systems are indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indications include symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), re-operation for failed fusion, or instability following surgery for the above indications.

The UNIPLATE and UNIPLATE 2 Anterior Cervical Plate Systems and the EAGLE Plus Micro Anterior Cervical Plate System are also indicated for treatment of spinal stenosis.

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Material: Implant Grade Titanium Alloy (ASTM F136)

Comparison to Predicate Device: The subject devices maintain the design characteristics of the previously cleared predicate devices. The subject devices include a claim regarding MR compatibility.

Non-clinical Test Summary:

Tests and analyses were conducted following standards referenced below to support MR compatibility claims.

ASTM 2182-11a, “Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging”

ASTM 2213-06, “Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment”

ASTM 2052-15, “Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment”

ASTM 2119-07, “Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants”

Clinical Test Summary:

N/A

Conclusion:

The proposed devices are identical to the predicate devices and therefore determined to be substantially equivalent. The devices are determined to be MR conditional based on the results of testing completed according to FDA Guidance document *"Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment",* December 11, 2014.