DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 20, 2016

Medos International Sárl
% Jeffrey Shiffman, J.D., M.S.
Senior Regulatory Affairs Specialist
DePuy Spine, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K160879
Trade/Device Name: CONFIDENCE™ High Viscosity Spinal Cement, VIPER® and EXPEDIUM® Fenestrated Screw Systems
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: PML, MNI
Dated: November 17, 2016
Received: November 18, 2016

Dear Mr. Shiffman:

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)*
K160879

Device Name
CONFIDENCE™ High Viscosity Spinal Cement

Indications for Use *(Describe)*
When the CONFIDENCE™ High Viscosity Spinal Cement is used in conjunction with the VIPER® and EXPEDIUM® Fenestrated Screw Systems, the cement is 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The VIPER® and EXPEDIUM® Fenestrated Screw Systems augmented with the CONFIDENCE™ High Viscosity Spinal Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Type of Use *(Select one or both, as applicable)*

X 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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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)*
K160879

Device Name
VIPER® and EXPEDIUM® Fenestrated Screw Systems

Indications for Use *(Describe)*

When used in conjunction with CONFIDENCE™ High Viscosity Spinal Cement, the VIPER® and EXPEDIUM® Fenestrated Screw Systems are 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The VIPER® and EXPEDIUM® Fenestrated Screw Systems augmented with the CONFIDENCE™ High Viscosity Spinal Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

A. Submitter Information

Manufacturer:	Medos International Sárl Chemin-Blanc 38 2400 Le Locle, Switzerland
Submitter:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02767
Contact Person:	Jeffrey Shiffman, J.D., M.S. 325 Paramount Drive Raynham, MA 02767
Telephone number:	508-977-3857
Fax number:	508-828-3797
Email:	jshiffma@its.jnj.com

B. Date Prepared December 16, 2016

C. Device Name

Trade/Proprietary Name:	1) CONFIDENCE™ High Viscosity Spinal Cement 2) VIPER® and EXPEDIUM® Fenestrated Screw Systems
Common/Usual Name:	1) Polymethylmethacrylate (PMMA) bone cement; 2) Pedicle screw spinal system
Classification Name and Product Classification Code:	1) Bone cement, posterior screw augmentation per 21 CFR §888.3027 PML 2) Orthosis, Pedicle screw spinal fixation per 21 CFR §888.3070: MNI

D. Predicate Device Name

Primary: Medtronic KYPHON HV-R Fenestrated Screw Cement, CD HORIZON Fenestrated Screw Set, K152604
Reference: EXPEDIUM Verse Spine System, K142185
EXPEDIUM and VIPER Cortical Fix Screws, K110216
CONFIDENCE High Viscosity Spinal Cement, K112907, K060300

E. Device Description

1) The CONFIDENCE™ High Viscosity Spinal Cement is a self-curing, high viscosity, radiopaque acrylic bone cement (PMMA), previously cleared by FDA in premarket notifications K060300 and K112907. The formulation of the spinal cement has not changed from the original clearance.

2) The VIPER® and EXPEDIUM® Fenestrated Screw Systems are designed with a cortical fix screw shank that is fully cannulated with lateral fenestrations at the distal end which allow for the controlled delivery of CONFIDENCE™ High Viscosity Spinal Cement. The design of the distally fenestrated screws provides a controlled means to deliver PMMA cement into the vertebral body. The screws are available in diameters of 4.35, 5.0, 6.0, 7.0, 8.0, 9.0 and 10.0mm and lengths of 30-80mm (in 5mm increments). Screws with lengths of 30mm have three fenestrations and screw lengths of 35mm and longer have six fenestrations. The VIPER® fenestrated screws are compatible with the VIPER System, VIPER2 and EXPEDIUM 5.5 Spine Systems (K111136) and the EXPEDIUM fenestrated screws are compatible with the EXPEDIUM VERSE® System (K142185).

F. Intended Use

1) When CONFIDENCE™ High Viscosity Spinal Cement is used in conjunction with the VIPER® and EXPEDIUM® Fenestrated Screw Systems, the cement is 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The VIPER® and EXPEDIUM® Fenestrated Screw Systems augmented with the CONFIDENCE™ High Viscosity Spinal Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

2) When used in conjunction with CONFIDENCE™ High Viscosity Spinal Cement, the VIPER® and EXPEDIUM® Fenestrated Screw Systems are 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The VIPER® and EXPEDIUM® Fenestrated Screw Systems augmented with the CONFIDENCE™ High Viscosity Spinal Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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

1) CONFIDENCE™ High Viscosity Spinal Cement is cleared via K060300 and K112907. The sterilization method for the subject cement has not changed from K060300 and K112907, and incorporates bacterial endotoxin testing applying the 20 EU/mL pyrogen limit specification utilizing the Limulus amebocyte lysate (LAL) test.

   The difference between the predicate and subject cement is the delivery method of the cement. Although the cement delivery system is not changing, the additional delivery method and expanded indications enables the subject cement to be delivered through the cannulated fenestrated screw for a controlled flow of cement into the pedicle.

   CONFIDENCE™ High Viscosity Spinal Cement is similar to the Medtronic KYPHON HV-R Fenestrated Screw Cement (K152604) as both devices are viscous, polymethylmethacrylate material that hardens over time. After a screw is placed posteriorly within a prepared bone canal, the cement is delivered through the cannulated screw and out through the distal fenestrations. Both the predicate and proposed devices are intended to augment the fixation of screws in a posterior spinal system construct.

2) The VIPER® and EXPEDIUM® Fenestrated Screw Systems are similar to Medtronic CD Horizon Fenestrated screws (K152604). The proposed screw designs are similar to the predicate with fully cannulated screw shanks with side fenestrations at the distal tip to allow cement delivery. The intended use is similar as both the predicate and proposed devices are intended to provide immobilization and stabilization of spinal segments.

H. Materials

1) The powder component of the CONFIDENCE™ High Viscosity Spinal Cement is composed of acrylic polymer, benzoyl peroxide and barium sulphate. The liquid component of the CONFIDENCE™ High Viscosity Spinal Cement contains both methyl methacrylate monomer, hydroquinone (HQ) and N, N-Dimethyl-p-Toluidine (DMpT). The complete material composition of CONFIDENCE™ High Viscosity Spinal Cement can be found in K060300 and K112907.

2) The VIPER® and EXPEDIUM® Fenestrated Screw Systems are manufactured from ASTM F 136 implant grade titanium alloy and ASTM F1537 cobalt chromium alloy.

I. Performance Data

Non-clinical testing and clinical data were submitted to characterize the subject components in this notification. The data provided supports the substantial equivalence of the subject devices.

J. Conclusion

The performance testing, clinical literature, and substantial equivalence justification demonstrate that the device is as safe, as effective, and performs as well as the predicate device.