## 510(K) SUMMARY

DEC 2 8 2012

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| **Submitter:** | Medos International Sàrl<br>Chemin-Blanc 38<br>Le Locle, CH-NE 2400, Switzerland |
| **Contact Person:** | Eugene Bang<br>Regulatory Affairs Associate<br>Voice: (508) 977-3966<br>Fax: (508) 828-3797 |
| **Date Prepared:** | October 8, 2012 |
| **Trade Name:** | DePuy PULSE™ Anterior Cervical In-Line Plate System |
| **Device Class:** | Class II |
| **Product Code(s):** | KWQ |
| **Common Name:** | Appliance, Fixation, Spinal Intervertebral Body |
| **Classification Name:** | Spinal Intervertebral Body Fixation Orthosis |
| **Regulation Number:** | 888.3060 |
| **Predicate Devices:** | AcroPlate Anterior Cervical Plate System (DePuy Spine) – K914362<br>Uniplate Anterior Cervical Plate System (DePuy Spine) – K042544<br>Skyline Anterior Cervical Plate System (DePuy Spine) – K103491<br>PULSE Anterior Cervical Plate System (DePuy Spine) – K112724 |
| **Device Description:** | The DePuy PULSE Anterior Cervical In-Line Plate System is intended for anterior screw fixation of the plate to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with bone screws using an anterior approach.<br>The DePuy PULSE Anterior Cervical In-Line Plate System consists of an assortment of implantable titanium alloy plates and screws in various sizes. |

**Indications:**

The DePuy PULSE Anterior Cervical In-Line Plate System is intended for anterior cervical intervertebral body fixation. This system is 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.

Indication includes 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), spinal stenosis, re-operation for failed fusion, or instability following surgery for the above indications.

**Materials:**

Manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F-136.

**Comparison to Predicate Device:**

The substantial equivalence of the subject device to the predicates indentified above is based upon the equivalence of intended use, design (fundamental scientific technology), materials, manufacturing methods, performance, sterility, biocompatibility, safety and packaging design.

**Non-clinical Test Summary:**

The following mechanical tests were conducted:

- Static compression bending testing in accordance with ASTM F-1717 Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Model. The acceptance criteria was/were met.
- Static torsion testing in accordance with ASTM F-1717 Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Model. The acceptance criteria was/were met.
- Dynamic compression bending testing in accordance with ASTM F-1717 Standard Test Method for Spinal Implant Constructs in a Vertebrectomy Model. The acceptance criteria was/were met.

**Clinical Test Summary:**

No clinical tests were performed.

**Conclusion:**

Based on the predicate comparison and testing, the subject device DePuy PULSE Anterior Cervical In-Line Plate System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter dated: December 28, 2012

Medos International, Sarl
% John & Johnson Company
Mr. Eugene Bang
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K123167
Trade/Device Name: DePuy PULSE™ Anterior Cervical In-Line Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 08, 2012
Received: October 09, 2012

Dear Mr. Bang:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K123167

Device Name: DePuy PULSE™ Anterior Cervical In-Line Plate System

Indications For Use:

The DePuy PULSE Anterior Cervical In-Line Plate System is intended for anterior cervical intervertebral body fixation. This system is 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.

Indication includes 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), spinal stenosis, re-operation for failed fusion, or instability following surgery for the above indications.

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| Prescription Use ___X___ | AND/OR | Over-The-Counter Use _____ |
| (Part 21 CFR 801 Subpart D) | | (Part 21 CFR 807 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(K) Number: K123167