Dear Mr. Lainez:

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 (DICE) 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 (DICE) 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,

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

Enclosure
Indications for Use

The NEO Pedicle Screw System™ is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. The system is intended for posterior, non-cervical fixation for the following indications: 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, tumor, pseudarthrosis, and/or failed previous fusion.

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.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) Summary

| Date prepared | August 16, 2017, according to 21 CFR 807.92 |

### Purpose of submission

<table>
<thead>
<tr>
<th>510(k) type</th>
<th>Traditional 510(k)</th>
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<tr>
<td>Purpose of submission</td>
<td>Introduction of a new spinal system</td>
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### Submitter information

<table>
<thead>
<tr>
<th>Submitter</th>
<th>Neo Medical S.A. Route de Lausanne 157 A 1096 Villette (Lavaux), Switzerland</th>
</tr>
</thead>
<tbody>
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### Device name and classification

<table>
<thead>
<tr>
<th>Trade name</th>
<th>NEO Pedicle Screw System™</th>
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<tr>
<td>Common name</td>
<td>Pedicle screw spinal system</td>
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<tr>
<td>Device panel</td>
<td>Orthopedic</td>
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<tr>
<td>Classification name</td>
<td>Thoracolumbosacral Pedicle Screw System</td>
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<tr>
<td>Class</td>
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<td>NKB</td>
</tr>
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<td>CFR section</td>
<td>888.3070</td>
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### Predicate devices

The Neo Pedicle Screw System™ is substantially equivalent to the primary predicate 'Safe Orthopedics SteriSpine PS System' (K112453) and additional predicates DePuy Synthes 'Expedium, VIPER/VIPER2 System' (K111136, K131802) as well as the 'Joimax Percusys System' (K143200).
Indications for use

The NEO Pedicle Screw System™ is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. The system is intended for posterior, non-cervical fixation for the following indications: 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, tumor, pseudarthrosis, and/or failed previous fusion.

Device description

The NEO Pedicle Screw System™ consists of pedicle screws and connecting rods which differ in length and diameter. The system includes the relevant instruments which are single use, disposable and delivered sterile. All components and instruments are sterilized by gamma irradiation.

The screws are offered in diameters of 5.0 - 7.0 mm and lengths of 35 - 55 mm. Three different types of rods are available: pre-bent, straight or special bent rod for S1/L5. All rods have a diameter of 5.5 mm. Pre-bent rods are offered in lengths of 40 – 100 mm, straight rods in lengths from 30 - 300 mm and the special-bent rod in either 30 or 40 mm length. All spinal implant components are made of titanium alloy (Ti6Al4V Eli) in accordance with ASTM F136. The screws are color coded for better identification of the different diameters. The screws are double threaded, cannulated, fenestrated and self-tapping.

Summary of testing

Sterilization validation: Validated using VDmax method as described in ISO 11137-2 and confirmed a Sterility Assurance Level SAL of $10^{-6}$.

Pyrogenicity: LAL-Test (Limulustest) showed result below the detection limit of the test system.

Packaging validation: The sterile barrier system complies with ISO 11607-1. Real time and accelerated ageing studies as well as transport studies were performed to demonstrate 5 year shelf life and packaging integrity.

Biocompatibility: Biological evaluation has been performed in accordance with ISO 10993-1. Chemical Analysis according to ISO 10993-18 and Cytotoxicity testing were performed on worst case components of the NEO Pedicle Screw System™.

Mechanical testing: The following mechanical tests were performed in accordance with ASTM F1717: static and dynamic axial compression and static torsion. The results revealed that the NEO Pedicle Screw System™ is comparable with regards to mechanical strength to other currently marketed pedicle screw systems.

MRI Compatibility: The following tests were performed Magnetic field interactions ASTM F2052-15, MRI-related heating ASTM F2182-11a and Artifacts ASTM F2119-07 (R2013). The NEO Pedicle Screw System™ is MRI conditional an information is provided in the labeling.
**Monoaxial mode**: Verification of this unique feature showed that lock of the polyaxial screw with a clip performs as intended.

**Usability**: Suitability of the instruments and use of the NEO Pedicle Screw System™ including its labeling was confirmed in a WetLab study with orthopedic surgeons.

**Clinical Evaluation**: Based on review scientific literature, comparison with similar device and non-clinical performance data. Clinical studies were not required.

**Conclusion**

The NEO Pedicle Screw System™ is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function. Non-clinical performance testing demonstrate that the NEO Pedicle Screw System™ meets the requirements for Pedicle screw spinal systems according to Spinal System 510(k)s Guidance for Industry and FDA Staff Document issued on: May 3, 2004 and is as safe, as effective, as its predicate devices.