Neo Medical S.A.
Jonas Larsson
CEO
Route de Lausanne 157A
Villette (Lavaux), Vaud, 1096, Switzerland

Re: K181048
Trade/Device Name: Neo Cage System™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 28, 2018
Received: December 31, 2018

Dear Jonas Larsson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Hwang -S

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181048

Device Name
Neo Cage System™

Indications for Use *(Describe)*

Neo Cage System™ is an intervertebral body fusion device intended to be used with autogenous bone graft to facilitate interbody fusion and to be used with supplemental spinal fixation systems that have been cleared for the use in the lumbosacral spine. The cage is to be implanted in open surgery via a posterior or transforaminal approach.

The indication for use is Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have grade 1 Spondylolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

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.

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510(k) Summary

Date prepared	December 10, 2018, according to 21 CFR 807.92

Purpose of submission

510(k) type	Traditional 510(k)
Purpose of submission	Introduction of a new cage system

Submitter information

Submitter	Neo Medical S.A. Route de Lausanne 157 A 1096 Villette (Lavaux), Switzerland
Contact US agent confinis corporation	Mr. Charles Cathlin Mailto: charles.cathlin@confinis.com Phone: +1 240 252 0891

Device name and classification

Trade name	NEO Cage System™
Common name	Intervertebral body fusion device
Device panel	Orthopedic
Classification name	Intervertebral body fusion device
Class	II
Product code	MAX
CFR section	888.3080

Predicate devices

The Neo Cage System™ is substantially equivalent to the primary predicate device Stryker Tritanium Cage (K152304) as well as the following additional predicate devices: Spineart Juliet Ti (K153621), Medtronic Capstone (K073291 (initial), K082342 (PEEK introduced)) and SpineVision SpaceVision System (K153783).

Indications for use

Neo Cage System™ is an intervertebral body fusion device intended to be used with autogenous bone graft to facilitate interbody fusion and to be used with supplemental spinal fixation systems that have been cleared for the use in the lumbosacral spine. The cage is to be implanted in open surgery via a posterior or transforaminal approach.

The indication for use is Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have grade 1 Spondylolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Device description

The NEO Cage System™ is an intervertebral fusion device with autogenous bone graft intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The cages are intended to be used with supplemental spinal fixation systems that have been cleared for the use in the lumbosacral spine. The cage implants may be implanted via an open posterior approach.

The Neo Cage System™ consists of cages of different lengths, sizes and lordotic angles to adapt to a variety of patient anatomies. The size and form of the devices is adjusted to the morphology of the body and the surgical technique. The cages of the Neo Cage system are made of titanium alloy according to ISO 5832-3 or ASTM F3001 and are supplied sterile. The system includes the relevant instruments which are single use only and delivered sterile. The Instruments are to be used for the implantation of the above mentioned medical devices.

Summary of testing

Sterilization validation: The minimal dose of 25kGy is validated using VDmax^{25} method as described in ISO 11137-2 and confirmed a Sterility Assurance Level SAL of 10^{-6}.

Pyrogenicity: The pyrogenicity is tested with the LAL-Test (Limulustest). The results for endotoxin levels for all runs were <1.2 EU/device.

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 according to ISO 10993-5 were performed on worst case components of the NEO Cage System™.

Mechanical testing: Mechanical testing has been successfully completed.
The following tests were performed in accordance with ASTM F2077

- Static compression test
- Static shear compression test
- Static torsion test
- Dynamic compression test
- Dynamic shear compression test
- Dynamic torsion test

Additional testing included

- Subsidence test according to ASTM F2267
- Wear testing (debris) according to ISO 17853
- Expulsion test

Trabecular structure: The trabecular structure has been characterized by tomography examination.

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 Cage System™ is MRI conditional and information is provided in the labeling.

Clinical Evaluation: Clinical studies were not required, based upon review an evaluation of scientific literature, comparison with similar devices and non-clinical performance data.

Conclusion

The NEO Cage System™ is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function.
Non-clinical performance testing demonstrates that the NEO Cage System™ meets the requirements according to FDA Guidance for Intervertebral Body Fusion Device, issued on: June 12, 2007 and is as safe and effective, as its predicate devices.