DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 15, 2016

NLT SPINE Ltd.
% John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K153665
Trade/Device Name: PROW FUSION-L
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 16, 2016
Received: August 16, 2016

Dear Dr. Smith:

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 Parts 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" (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 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 on last page

510(k) Number *(if known)*

K153665

K153665

Device Name

PROW FUSION-L

Indications for Use *(Describe)*

The PROW FUSION-L is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 through S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The patient may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PROW FUSION-L device. The device is intended to be used with autogenous bone graft and a supplemental spinal fixation system that have been cleared for use in the lumbosacral spine (e.g. posterior pedicle screw and rod systems).

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.

510(k) SUMMARY

NLT SPINE's PROW FUSION-L

As required by 21 C.F.R. § 807.92

Sponsor:

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Date Prepared: September 13, 2016

Name of Device: PROW FUSION-L

Common or Usual Name: Intervertebral body fusion device
Classification Name: Intervertebral body fusion device
21 CFR §880.3080
Product Code MAX

Predicate Device

Primary predicate: Life Spine, Longbow Spacer System (K133717)

Additional predicates: NLT SPINE, PROW FUSION (K112359, K130254, K151654), PROW FUSION-V (K153786); Zimmer, BAK-L (K143297); Medtronic, CLYDESDALE® Spinal System (K132897); Stryker, ARIATM Spinal System (K143163); Globus, Caliber (K123231);TranS1 Lateral Intervertebral Fusion Device (K100210)

Intended Use / Indications for Use

The PROW FUSION-L is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 through S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and

radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The patient may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PROW FUSION-L device. The device is intended to be used with autogenous bone graft and a supplemental spinal fixation system that have been cleared for use in the lumbosacral spine (e.g. posterior pedicle screw and rod systems).

Device Description

PROW FUSION-L is lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. PROW FUSION-L is provided in different sizes to fit the anatomical needs of a wide variety of patients. PROW FUSION-L is manufactured from titanium alloy per ASTM F136 and Polyetheretherketone per ASTM F 2026. The device contains an expandable mechanism that allows it to achieve its final footprint in situ. PROW FUSION-L is to be filled with autogenous bone graft material.

Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae. The devices require the use of commercially available supplemental spinal fixation systems.

Summary of Technological Characteristics

The PROW FUSION-L is an intervertebral body fusion device designed for placement into a prepared disc space following discectomy, maintain the height of the disc space and promote interbody fusion, all in a manner substantially similar to the predicate device. The placement technique of the PROW FUSION-L and the predicate is identical. Both the PROW FUSION-L and the predicate are manufactured from titanium alloy and PEEK. Both devices create a closed volume for bone graft between their members after expansion.

Performance Data

Mechanical testing consisting of static and dynamic axial compression, static and dynamic compression-shear according to ASTM F2077 and subsidence according to ASTM F2267 was conducted in accordance with "Class II Special Controls Guidance Document: Intervertebral Fusion Device", June 12, 2007 to demonstrate substantial equivalence to the predicate. In addition, expulsion and wear particle assessment testing was also performed.

Conclusions

PROW FUSION-L is similar to the predicate with respect to technical characteristics, performance and intended use. The information provided within this premarket notification supports substantial equivalence of the subject PROW FUSION-L to the predicate device.