510(k) Summary

Sponsor:

NLT SPINE Ltd.
6 Yoni Nethanyahu St.
Or-Yehuda
Israel

Contact Person:

Eti Zinger
Regulatory Affairs Director
NLT SPINE Ltd.
Tel: +972-3-6343321
Fax: +972-3-6341599
Eti.z@nlt-spine.com

Date Prepared: November 1, 2011

Name of Device: Prow Fusion

Common or Usual Name: Intervertebral body fusion device

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

Predicate Devices

- Custom Spine Pathway AVID (K090566)
- Integra Spine Vu aPOD (K080822)

Intended Use / Indications for Use

The Prow Fusion is intended to be used for spinal fusion.

The Prow-Fusion Intervertebral body fusion device is indicated for spinal fusion procedures at one or two contiguous levels from L2 through S1 in skeletally mature patients with degenerative disc disease (DDD). 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).

The device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (e.g. posterior pedicle screw and rod systems). The device is intended to be used with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Prow Fusion device.

The Prow Fusion intervertebral body fusion device must be inserted using a transforaminal approach.

Technological Characteristics

The Prow Fusion Intervertbral Body Fusion Device system is comprised of two components. One component is the single-use Prow Fusion implant (intervertebral body fusion device) of various heights and the second component is a set of reusable instruments (the Prow Fusion Delivery System) used for its implantation. The implant is made from PEEK enriched with carbon fibers (CFPEEK) and titanium alloy. The implant features multiple CFPEEK mid segments and titanium end segments. The segments are serrated on the superior and inferior surfaces and are attached with titanium pins.

The Prow Fusion intervertebral body fusion implant is inserted using a transforaminal approach. The proximal and the distal segments are bound together by ultra high molecular weight poly ethylene (UHMWPE) suture. The suture is used to pull the distal segment proximally to form a ring-shaped, closed-configuration implant in the disc space.

Performance Data

Performance data per ASTM F2077 (Static axial compression, static compression shear, static torsion, dynamic axial compression, dynamic compression shear and dynamic torsion) and ASTM F2267 (Subsidence), expulsion and wear testing was conducted following a recognized protocol and compared to the predicate devices. In addition, cadaver testing demonstrated the Prow Fusion is substantially equivalent to its predicates, as it was shown that the device can be used as intended by the intended user population per its labeling following a standard training program.

Substantial Equivalence

The Prow Fusion is as safe and effective as its predicate devices. The Prow Fusion has substantially similar indications for use and technological characteristics as compared to the predicate devices. Any minor differences between the device and predicates do not raise new questions of safety and effectiveness. Further, performance testing has established that the Prow Fusion has equivalent performance and safety as compared to the claimed predicates. Thus, the device is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NOV - 8 2011

NLT Spine Ltd.
% Hogan and Lovells US, LLP
John J. Smith, M.D., J.D.
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K112359
Trade/Device Name: Prow Fusion
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 16, 2011
Received: August 16, 2011

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.

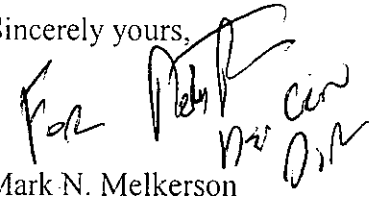
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Statement of Indications for Use

510(k) Number (if known): K112359

Device Name: **Prow Fusion**

Indications for Use:

The Prow-Fusion Intervertebral body fusion device is intended for spinal fusion procedures at one or two contiguous levels from L2 through S1 in skeletally mature patients with degenerative disc disease (DDD). 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).

The device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (e.g. posterior pedicle screw and rod systems). The device is intended to be used with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Prow Fusion device.

The Prow Fusion intervertebral body fusion device must be inserted using a transforaminal approach.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112359