DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 27, 2017

Nexus Spine, LLC
Mr. Jared Crocker
Director of Quality and Regulatory Affairs
2825 East Cottonwood Parkway, Suite 330
Salt Lake City, Utah 84121

Re: K170297
Trade/Device Name: Tranquil Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: May 24, 2017
Received: May 25, 2017

Dear Mr. Crocker:

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 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 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 below.

510(k) Number *(if known)*
K170297

Device Name

Tranquil Interbody System

Indications for Use *(Describe)*

The Tranquil™ Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion.

The Tranquil™ Cervical Interbody System is intended for spinal fusion procedures at one level in the cervical spine (C3 to C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. The cervical device is to be implanted via an open, anterior approach and packed with autogenous bone. The cervical device is to be used in patients who have had six weeks of non-operative treatment. This device system is intended for use with supplemental internal fixation systems.

The Tranquil™ Lumbar Interbody System is intended for use at either one level or two contiguous levels (L2-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 history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The patients may have had a previous non-fusion spinal surgery at the involved level(s). The device is intended to be used with supplemental internal fixation 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.

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510(k) Summary

Submitter: Nexus Spine, LLC

Contact Person: Mr. Jared Crocker, Director of Quality and Regulatory Affairs
2825 East Cottonwood Parkway, Suite 330
Salt Lake City, UT 84121
Telephone: (801) 702-8592
Fax: (801) 702-8585

Date Prepared: June 26, 2017

Trade Name: Tranquil Interbody System

Classification, Name and Number: Class II
Intervertebral body fusion device
21 CFR 888.3080

Product Code: MAX, ODP

Predicate Device(s):

Manufacturer	Device	510(k)/PMA Number
Primary Predicate		
K2M	Cascadia Interbody System	K160547
Other Predicates		
Adaptive Specialty	Fusion Advantage Cervical Cage Fusion Advantage Lumbar Cage	K083425
K2M	Aleutian	K130699
Spinal Elements	Lucent	K071724/ K081968
Spinal Elements	Crystal Cervical Cage	K073351
LDR Spine	Cervical Interbody Fusion System	K091088
Meditech	Talos PLIF	K090707
Captiva Spine	PivoTEC Lumbar Interbody Fusion Device (LFID)	K092017

Device Description: The Tranquil Interbody System is made of Ti-6Al-4V ELI. The implant is offered in various angles, widths, heights, and lengths to meet patient anatomy for both cervical and lumbar spine. The devices and instruments

are provided clean and non-sterile for steam sterilization at the user's facility.

Intended Use: The Tranquil™ Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion.

The Tranquil™ Cervical Interbody System is intended for spinal fusion procedures at one level in the cervical spine (C3 to C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. The cervical device is to be implanted via an open, anterior approach and packed with autogenous bone. The cervical device is to be used in patients who have had six weeks of non-operative treatment. This device system is intended for use with supplemental internal fixation systems.

The Tranquil™ Lumbar Interbody System is intended for use at either one level or two contiguous levels (L2-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 history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The patients may have had a previous non-fusion spinal surgery at the involved level(s). The device is intended to be used with supplemental internal fixation systems.

Statement of Technological Comparison: The Tranquil Interbody System is manufactured using additive manufacturing, but the predicate devices are machined of the same material. This difference does not impact the substantial equivalence of the devices. The Tranquil Interbody System is substantially equivalent to the above listed predicate devices in terms of materials, design, indications for use and operational principles.

Performance Data: Verification activities based on ASTM F2077, ASTM F2267 and expulsion testing were performed. The mechanical testing demonstrated the device can be expected to perform in a manner substantially equivalent to the predicates listed above.

Conclusion: Documentation provided demonstrates the Tranquil Interbody System is substantially equivalent to predicate devices.