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

August 27, 2018

Re: K181483
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: August 6, 2018
Received: August 8, 2018

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. 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,

Brent Showalter -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)*

K181483

Device Name
Tranquil™ Interbody System

Indications for Use *(Describe)*

Tranquil-C™ Interbody System

The Tranquil-C™ Interbody System is intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 – T1. The Tranquil-C™ Interbody System is also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. The Tranquil-C™ Interbody System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Tranquil-L™ Interbody System

The Tranquil-L™ Interbody System is intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 – S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone.

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
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Date Prepared: August 6, 2018

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) Number
Primary Predicate		
Nexus Spine LLC	Tranquil™ Interbody System	K170297
Additional Predicates		
HD LifeSciences LLC	HD Lumbar Interbody System	K170676
EIT Emerging Implant Technologies GmbH	EIT Cellular Titanium Cervical Cages, EIT Cellular Titanium PLIF Cages, EIT Cellular Titanium TLIF Cages, EIT Cellular Titanium ALIF Cages	K172888

Reference Device(s): The following devices have been 510(k) cleared with these same or similar technological elements: ODP product code, indications for use including autograft and/or allograft, and anatomical region (multiple contiguous levels from C2 – T1):

- NuVasive: Modulus-C Interbody System (K172676)
- Astura Medical: ALTA Anterior Cervical Interbody Spacer (K173324)
- NuVasive: Cohere Cervical Interbody Fusion Device (K173030)
- NuVasive: CoRoent Small Interbody System (K163491)

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.

The purpose of this traditional 510(k) is to expand the indications for use to include use with either autograft and/or allograft bone for the Tranquil™ Interbody System, as well as update the fusion level for the Tranquil-C™ Interbody System to include use at multiple levels (e.g., up to 4 levels) from C2 – T1, and add additional footprints.

Intended Use:

Tranquil-C™ Interbody System

The Tranquil-C™ Interbody System is intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 – T1. The Tranquil-C™ Interbody System is also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. The Tranquil-C™ Interbody System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Tranquil-L™ Interbody System

The Tranquil-L™ Interbody System is intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 – S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone.

Statement of Technological Comparison:

The technological principle for both the subject and the primary predicate device is intervertebral body fusion of the spine in skeletally mature patients with degenerative disc disease.

The subject device, Tranquil™ Interbody System, and the primary predicate device, Tranquil™ Interbody System (K170297), are based on the following technological elements:

- Same FDA Product Codes: MAX, ODP
- Same implant material: Ti-6Al-4V
- Same manufacturing process: Additive
- Similar indications for use
- Equivalent multiple footprints, geometries, and heights to account for variations in patient anatomy
- Equivalent anatomical region
- Same surgical approach

The difference between the subject device and the primary predicate device is the addition of new footprints, as well as the expanded indications as described in the following paragraphs.

Tranquil-L™ Interbody System

The primary predicate Tranquil-L™ Interbody System is already cleared to be used with autogenous bone graft (autograft). The proposed indication for the subject Tranquil-L™ Interbody System is to include the use of allograft.

The additional predicate device, HD Lumbar Interbody System (K170676) is equivalent to the subject device in the following technological elements:

- Same FDA product code: MAX
- Equivalent implant material: Ti-6Al-4V
- Equivalent manufacturing process: Additive
- Same Indications for Use: including autograft and/or allograft
- Same anatomical region: up to 2 levels from L2 – S1
- Equivalent multiple footprints, geometries, and heights to account for variations in patient anatomy
- Same surgical approach

As these technological characteristics of the subject Tranquil-L™ Interbody System are equivalent to those of predicate K170676, the use of cancellous and/or corticocancellous allograft in the Tranquil-L™ Interbody System may also be deemed equivalent.

Tranquil-C™ Interbody System

The primary predicate Tranquil-C™ Interbody System is already cleared to be used with autogenous bone graft (autograft) and is intended to be used for procedures at one level from C3 – C7. The proposed indication for the subject Tranquil-C™ Interbody System is to include the use of allograft for procedures at multiple levels (e.g., up to 4 levels) from C2 – T1.

The additional predicate device, EIT Cellular Titanium Cervical Cages (K172888), is equivalent to the subject device in the following technological elements:

- Same FDA product code: ODP
- Equivalent implant material: Ti-6Al-4V
- Equivalent manufacturing process: Additive
- Same Indications for Use: including autograft and/or allograft
- Same anatomical region: multiple levels from C2 – T1
- Equivalent multiple footprints, geometries, and heights to account for variations in patient anatomy
- Same surgical approach

Reference Devices:
In addition to the additional predicate device, EIT Cellular Titanium Cervical Cages, many other 510(k) cleared devices have the same or similar technological elements:

- Same FDA product code: ODP
- Same Indications for Use: including autograft and/or allograft
- Same anatomical region: multiple levels from C2 – T1
- Equivalent multiple footprints, geometries, and heights to account for variations in patient anatomy
- Same surgical approach

In the years 2017 and 2018, there were at least four devices with the technological elements stated above which received 510(k) clearance:

- NuVasive: Modulus-C Interbody System (K172676)
- Astura Medical: ALTA Anterior Cervical Interbody Spacer (K173324)
- NuVasive: Cohere Cervical Interbody Fusion Device (K173030)
- NuVasive: CoRoent Small Interbody System (K163491)

Therefore, the expansion of the Tranquil-C™ Interbody System indications for use to include allograft at multiple levels from C2 – T1 is substantially equivalent to the predicate devices.

Performance Data: Mechanical performance testing data was provided as part of the previous submission to establish substantial equivalence for its use. As was demonstrated in this submission through engineering rationale, the additional footprints do not present a new worst case for the testing that was previously performed. Therefore, no new mechanical testing was performed for this 510(k) submission.

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