January 9, 2020

Nexxt Spine LLC
% Karen E. Warden, PhD
President
BackRoads Consulting
PO Box 566
Chesterland, Ohio 44026

Re: K192687
Trade/Device Name: TrellOss™-L MPF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: November 12, 2019
Received: November 13, 2019

Dear Dr. Warden:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, PhD
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K192687

Device Name
TrellOss™-L MPF

Indications for Use *(Describe)*

When used as a lumbar intervertebral fusion device, TrellOss™-L MPF is indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, TrellOss™-L MPF can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. TrellOss™-L MPF is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.
TrellOss™-L MPF interbody implants with 14° lordosis or greater are only indicated for lumbar levels L2–L5 and are to be used with at least a 1-hole Timberline® MPF plate and screw construct.

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

Date:	25 September 2019
Sponsor:	Nexxt Spine, LLC 14425 Bergen Blvd, Suite B Noblesville, IN 46060 Office: 317.436.7801 Fax: 317.245.2518
Sponsor Contact:	Andy Elsbury, President
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	TrellOss™-L MPF
Common Name:	Interbody fusion device
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Intervertebral fusion device with bone graft, lumbar, 888.3080, MAX Intervertebral fusion device with integrated fixation, lumbar, 888.3080, OVD
Submission Purpose:	The subject 510(k) adds a lateral interbody, the TrellOss™-L MPF, to the NEXXT MATRIXX® System.
Device Description:	TrellOss™-L MPF is a 3D printed, lateral interbody fusion device. The inferior/superior aspects of the TrellOss™-L MPF interbody incorporates two large vertical cavities which can be packed with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft material. Each interbody comprises an external structural frame having a roughened surface (~7µm). The intervening geometric lattices have pores 300-700µm. The TrellOss™-L MPF interbody can be used in conjunction with the Timberline® MPF plates and screws. The plate implants are offered having 1-, 2-, 3- or 4-holes to accommodate the vertebral screws. Cover plates secure the construct. TrellOss™-L MPF interbody implants are provided sterile while the Timberline® MPF plate and screw implants are provided non-sterile. All devices are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient.
Indications for Use:	When used as a lumbar intervertebral fusion device, TrellOss™-L MPF is indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Additionally, TrellOss™-L MPF can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. TrellOss™-L MPF is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation. TrellOss™-L MPF interbody implants with 14° lordosis or greater are only indicated for lumbar levels L2–L5 and are to be used with at least a 1-hole Timberline® MPF plate and screw construct.

Materials:	TrellOss™-L MPF interbody implants are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F3001). The Timberline® MPF plate and screw implants are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136).
Primary Predicate:	NEXXT MATRIXX® System (Nexxt Spine, LLC – K171140)
Additional Predicates:	Biomet Fusion System (Biomet Spine – K163543)
Performance Data:	The modified TrellOss™-L MPF interbody was evaluated via dimensional analyses with confirmatory static compression and dynamic compression shear testing per ASTM F2077. The results demonstrated the performance of the modified TrellOss™-L MPF is substantially equivalent to the predicate.
Technological Characteristics:	The modified TrellOss™-L MPF interbody possesses the same technological characteristics as one or more of the predicate devices. These include: • performance (as described above), • basic design (additively manufactured structural interbody), • material (titanium alloy) and • size (dimensions are comparable to those offered by cleared devices). Therefore the fundamental scientific technology of the modified TrellOss™-L MPF is the same as previously cleared devices.
Conclusion:	The modified TrellOss™-L MPF possesses the same intended use and technological characteristics as the predicate devices. Therefore the modified TrellOss™-L MPF is substantially equivalent for its intended use.