December 15, 2020

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

Re: K202230
Trade/Device Name: NEXXT MATRIXX® Stand Alone ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: November 18, 2020
Received: November 19, 2020

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 L. Showalter, Ph.D.
Assistant Director
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)*

K202230

Device Name
NEXXT MATRIXX® Stand Alone ALIF System

Indications for Use *(Describe)*

The NEXXT MATRIXX® Stand Alone ALIF System is a stand-alone anterior lumbar interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (L2-S1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels and should have received at least six months of nonoperative treatment prior to treatment with the device. The NEXXT MATRIXX® Stand Alone ALIF System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. Hyperlordotic interbody devices (>20° lordosis) must be used with supplemental fixation (e.g. posterior fixation). Each interbody fusion device having a lordotic angle 20° or less is intended to be used with the bone screws provided and requires no additional fixation.

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:	7 August 2020
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:	NEXXT MATRIXX® Stand Alone ALIF System
Common Name:	Lumbar interbody with integrated fixation
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Intervertebral fusion device with integrated fixation, lumbar, 888.3080, OVD
Device Description:	NEXXT MATRIXX® is a collection of additively manufactured implants. The Stand Alone ALIF System includes additively manufactured interbody and traditionally machined fixation screw implants. The interbody and screw components are available in an assortment of dimensional combinations to accommodate the individual anatomic and clinical circumstances of each patient. The basic shape of the interbody is a structural column to provide surgical stabilization of the spine. Each device comprises an external structural frame having a roughened surface (~7µm). The intervening geometric lattices have 300-700µm pores. The inferior/superior aspects of the interbody incorporates a vertical cavity which can be packed with bone graft material. Each interbody is preassembled with turn lock mechanisms which secure the screws to the interbody component.
Indications for Use:	The NEXXT MATRIXX® Stand Alone ALIF System is a stand-alone anterior lumbar interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (L2-S1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels and should have received at least six months of nonoperative treatment prior to treatment with the device. The NEXXT MATRIXX® Stand Alone ALIF System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. Hyperlordotic interbody devices (>20° lordosis) must be used with supplemental fixation (e.g. posterior fixation). Each interbody fusion device having a lordotic angle 20° or less is intended to be used with the bone screws provided and requires no additional fixation.
Materials:	NEXXT MATRIXX® Stand Alone ALIF System interbody implants are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001. The fixation screws and turn lock subcomponents are manufactured from Ti-6Al-4V ELI titanium alloy per F136.
Primary Predicate:	AXTi™ Titanium Stand-Alone ALIF System (Innovasis, Inc. – K182139)

Performance Data:	Mechanical testing of worst case NEXXT MATRIXX® Stand Alone ALIF System devices included subsidence, static and dynamic compression, and static and dynamic compression shear according to ASTM F2267 and ASTM F2077. In addition, expulsion and screw pushout properties were evaluated. The mechanical test results demonstrate that Stand Alone ALIF System performance is substantially equivalent to the predicate devices.
Technological Characteristics:	The NEXXT MATRIXX® Stand Alone ALIF System possesses the same technological characteristics as one or more of the predicate devices. These include: intended use (as described above), basic design (additively manufactured structure and integrated fixation), material (titanium alloy) and sizes (dimensions are comparable to those offered by the predicate systems). Therefore the fundamental scientific technology of the Stand Alone ALIF System is the same as previously cleared devices.
Conclusion:	The NEXXT MATRIXX® Stand Alone ALIF System possesses the same intended use and technological characteristics as the predicate devices. Therefore the Stand Alone ALIF System is substantially equivalent for its intended use.