February 24, 2020

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

Re: K193412
Trade/Device Name: NEXXT MATRIXX® System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PLR, MQP
Dated: December 23, 2019
Received: December 26, 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)*

K193412

Device Name
NEXXT MATRIXX® System

Indications for Use *(Describe)*

The NEXXT MATRIXX® corpectomy devices are indicated for use in the cervical spine (C2-T1) and thoracolumbar spine (T1-L5) in skeletally mature patients to replace a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders. The NEXXT MATRIXX® corpectomy devices are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. The NEXXT MATRIXX® corpectomy devices are intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion and with FDA-cleared supplemental internal 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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Section 7 – 510(k) Summary

Date:	6 December 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:	NEXXT MATRIXX® System
Common Name:	Corpectomy device
Device Classification:	Class II
Regulation Name, Regulation Number, Product Codes:	Spinal vertebral body replacement device - Cervical, 888.3060, PLR Spinal vertebral body replacement device, 888.3060, MQP
Submission Purpose:	The subject 510(k) adds a vertebral body replacement (corpectomy) device to the NEXXT MATRIXX® System.
Device Description:	The NEXXT MATRIXX® System is a collection of additively manufactured spacers for cervical, lumbar/lumbosacral and thoracolumbar implantation. The basic shape of these implants 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 pores 300-700µm. The inferior/superior aspects of the NEXXT MATRIXX® open devices incorporate a large vertical cavity which can be packed with bone graft material. The inferior/superior aspects of the NEXXT MATRIXX® solid devices are closed and do not permit the packing of bone graft within the implant. The solid devices are only to be used for partial vertebral body replacement. The open and solid devices are available in an assortment of height, length, width and lordotic angulation combinations to accommodate the individual anatomic and clinical circumstances of each patient.
Indications for Use:	The NEXXT MATRIXX® corpectomy devices are indicated for use in the cervical spine (C2-T1) and thoracolumbar spine (T1-L5) in skeletally mature patients to replace a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders. The NEXXT MATRIXX® corpectomy devices are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. The NEXXT MATRIXX® corpectomy devices are intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion and with FDA-cleared supplemental internal fixation.

Materials:	NEXXT MATRIXX® implants are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F3001).
Primary Predicate:	NEXXT MATRIXX® System (Nexxt Spine, LLC – K171140)
Additional Predicate:	Honour System (Nexxt Spine, LLC – K120345), Capri® Corpectomy Cage System (K2M Inc. – K180665)
Performance Data:	The modified corpectomy device was evaluated via mechanical testing including included static and dynamic compression and static and dynamic torsion (ASTM F2077), subsidence (ASTM F2267) and expulsion. The results demonstrated the performance of the modified corpectomy is substantially equivalent to the predicate.
Technological Characteristics:	The modified NEXXT MATRIXX® System corpectomy 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 the cleared devices). Therefore the fundamental scientific technology of the modified NEXXT MATRIXX® System corpectomy is the same as previously cleared devices.
Conclusion:	The modified NEXXT MATRIXX® System corpectomy possesses the same intended use and technological characteristics as the predicate devices. Therefore the modified NEXXT MATRIXX® System corpectomy is substantially equivalent for its intended use.