March 23, 2020

Nexxt Spine, LLC
% Karen E. Warden, Ph.D.
President
BackRoads Consulting Inc.
P.O. Box 566
Chesterland, Ohio 44026

Re: K200543
Trade/Device Name: NEXXT MATRIXX® Stand Alone Cervical-Turn Lock (-TL) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: March 2, 2020
Received: March 3, 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,

for Brent Showalter, Ph.D.
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)*

K200543

Device Name
NEXXT MATRIXX® Stand Alone Cervical-Turn Lock (-TL) System

Indications for Use *(Describe)*

The NEXXT MATRIXX® Stand Alone Cervical-TL System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of nonoperative treatment prior to treatment with the device. The NEXXT MATRIXX® Stand Alone Cervical-TL System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. The NEXXT MATRIXX® Stand Alone Cervical-TL System is intended to be used with the bone screw fixation 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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Section 7 – 510(k) Summary

Date:	2 March 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 Cervical-Turn Lock (-TL) System
Common Name:	Cervical spacer with integrated fixation
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Intervertebral fusion device with integrated fixation, cervical, 888.3080, OVE
Submission Purpose:	The subject 510(k) adds an line of implants having an alternative screw retention feature to the NEXXT MATRIXX® Stand Alone Cervical System.
Device Description:	NEXXT MATRIXX® is a collection of additively manufactured implants. The Stand Alone Cervical-TL System includes additively manufactured spacer and traditionally machined fixation screw implants. The spacer 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 spacer 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 spacer incorporates a vertical cavity which can be packed with bone graft material. Each interbody is preassembled with a turn lock mechanism which secures the screw to the spacer component.
Indications for Use:	The NEXXT MATRIXX® Stand Alone Cervical-TL System is a stand-alone anterior cervical interbody fusion system intended for use as an adjunct to fusion at one or two contiguous levels (C2-T1) in skeletally mature patients for the treatment of degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies). These patients should have received at least six weeks of nonoperative treatment prior to treatment with the device. The NEXXT MATRIXX® Stand Alone Cervical-TL System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. The NEXXT MATRIXX® Stand Alone Cervical-TL System is intended to be used with the bone screw fixation provided and requires no additional fixation
Materials:	NEXXT MATRIXX® Stand Alone Cervical System spacers are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001. The fixation screws and turn lock components are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F136.

Primary Predicate:	NEXXT MATRIXX® Stand Alone Cervical System (Nexxt Spine, LLC – K190546)
Performance Data:	The modified Stand Alone Cervical-TL device components were evaluated via dimensional analyses. The results demonstrated the performance of the modified Stand Alone Cervical-TL device is substantially equivalent to the predicate. In addition, the screw pushout properties for the modified Stand Alone Cervical-TL construct were evaluated.
Technological Characteristics:	The modified Stand Alone Cervical-TL device possesses the same technological characteristics as one or more of the predicate devices. These include: • performance (as described above), • basic design (additively manufactured structure and integrated fixation), • material (titanium alloy) and • size (dimensions are comparable to those offered by the cleared devices). Therefore the fundamental scientific technology of the modified Stand Alone Cervical-TL device is the same as previously cleared devices.
Conclusion:	The modified Stand Alone Cervical-TL System possesses the same intended use and technological characteristics as the predicate devices. Therefore the modified Stand Alone Cervical-TL System is substantially equivalent for its intended use.