



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

July 10, 2019

Re: K191408
Trade/Device Name: Nexxt Matrixx® System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 28, 2019
Received: July 1, 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,

for Melissa Hall
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

Indications for Use

510(k) Number (if known)

K191408

Device Name

Nexxt Matrixx® System

Indications for Use (Describe)

When used as a lumbar intervertebral fusion device, the Nexxt Matrixx® open devices are 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, the Nexxt Matrixx® lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental 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:	24 May 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 MATRIX [®] System
Common Name:	Interbody fusion system
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Intervertebral fusion device with bone graft, lumbar, 888.3080, MAX
Submission Purpose:	The subject 510(k) adds a steerable TLIF interbody device to the NEXXT MATRIX [®] System.
Device Description:	The NEXXT MATRIX [®] rTLIF is a collection of additively manufactured spacers for lumbar/lumbosacral 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 MATRIX [®] open devices incorporate a large vertical cavity which can be packed with autograft or allograft comprised of cancellous and/or corticocancellous bone graft material. The 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:	When used as a lumbar intervertebral fusion device, the NEXXT MATRIX [®] open devices are 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, the NEXXT MATRIX [®] lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.
Materials:	NEXXT MATRIX [®] implants are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F3001).
Primary Predicate:	NEXXT MATRIX [®] System (Nexxt Spine, LLC – K171140)
Additional Predicates:	Cascadia Interbody System (K2M Inc. – K172009)
Performance Data:	The modified rTLIF device was evaluated via finite element analyses and Dynamic Axial Compression per ASTM F2077. The results demonstrated the performance of the modified TLIF is substantially equivalent to the predicate.

**Technological
Characteristics:**

The modified NEXXT MATRIX[®] System rTLIF 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 MATRIX[®] System rTLIF is the same as previously cleared devices.

Conclusion:

The modified NEXXT MATRIX[®] System rTLIF possesses the same intended use and technological characteristics as the predicate devices. Therefore the modified NEXXT MATRIX[®] System rTLIF is substantially equivalent for its intended use.