



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Nexxt Spine, LLC  
% Karen Warden, PhD  
President  
BackRoads Consulting  
PO Box 566  
Chesterland, Ohio 44026-2141

August 22, 2017

Re: K171140  
Trade/Device Name: Matrixx™ System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: ODP, MAX, MQP  
Dated: July 21, 2017  
Received: July 24, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K171140

Device Name

Matrixx™ System

Indications for Use (Describe)

When used as a cervical intervertebral fusion device, the Matrixx™ System open devices are indicated for use at up to two contiguous levels in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

When used as a lumbar intervertebral fusion device, the Matrixx™ System 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 Matrixx™ System 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.

When used as a vertebral body replacement device, the Matrixx™ System open and solid devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft and with 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

---

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
*PRAStaff@fda.hhs.gov*

*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*

## **510(k) Summary**

**Date:** 17 April 2017

**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:** Matrixx™ System

**Common Name:** Spacer system

**Device Classification:** Class II

**Regulation Names,  
Regulation Numbers,  
Product Codes:** Spinal vertebral body replacement device, 888.3060, MQP  
Intervertebral fusion device with bone graft, 888.3080, lumbar/cervical,  
MAX/ODP

**Device Description:** The 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 Matrixx™ open devices incorporate a large vertical cavity which can be packed with bone graft material. The inferior/superior aspects of the 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:** When used as a cervical intervertebral fusion device, the Matrixx™ System open devices are indicated for use at up to two contiguous levels in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

When used as a lumbar intervertebral fusion device, the Matrixx™ System 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 Matrixx™ System 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.

When used as a vertebral body replacement device, the Matrixx™ System open and solid devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft and with supplemental internal fixation.

**Materials:** Matrixx™ System implants are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F3001) .

**Primary Predicate:** Primary: Cascadia Interbody System (K2M Inc. – K160125)

**Additional Predicates:** Additional: Honour System (Nexxt Spine, LLC – K120345), Lumbar I/F Cage (DePuy Spine – P960025)

**Performance Data:** Mechanical testing of worst case Matrixx™ System devices included static and dynamic compression, static and dynamic compression shear and static torsion according to ASTM F2077. In addition, the subsidence properties were evaluated according to ASTM F2267 and expulsion according to the ASTM draft standard. The manufactured surface was evaluated according to ASTM F1978.

The mechanical test results demonstrate that Matrixx™ System performance is substantially equivalent to the predicate devices.

**Technological Characteristics:** The Matrixx™ 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),
- material (titanium alloy),
- sizes (dimensions are comparable to those offered by the predicate systems) and

The Matrixx™ System is the same as previously cleared devices.

**Conclusion:** The Matrixx™ System possesses the same intended use and technological characteristics as the predicate devices. Therefore Matrixx™ System is substantially equivalent for its intended use.