September 17, 2020

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

Re: K202192
Trade/Device Name: STRUXXURE®-L and STRUXXURE®-A Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 4, 2020
Received: August 5, 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,

Colin O'Neill, M.B.E.
Acting 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)*

K202192

Device Name

STRUXXURE®-L and STRUXXURE®-A Plate System

Indications for Use *(Describe)*

The STRUXXURE®-L and STRUXXURE®-A Plate System is indicated for treatment of spine instability via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the thoracic and thoracolumbar (T1-L5) spine or via an anterior surgical approach below the bifurcation of the great vessels in the lumbar and lumbosacral (L1-S1) spine. The indications for use include fracture (including dislocation and subluxation), tumor, degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, spondylolysis, spondylolisthesis, pseudarthrosis and failed previous spine surgery.

The STRUXXURE®-L System may also be attached to NEXXT MATRIXX® Lateral interbody devices. The STRUXXURE®-A Plate System may also be attached to NEXXT MATRIXX® ALIF interbody devices. In these configurations the STRUXXURE®-L and STRUXXURE®-A Plate System is used to treat skeletally mature patients having DDD at one or two contiguous levels from L2-S1 with up to Grade 1 spondylolisthesis or as an adjunct to fusion in patients diagnosed with degenerative scoliosis.

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.**

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

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# Section 7 - 510(k) Summary

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| **Date:** | 4 August 2020 |
| **Sponsor:** | Nexxt Spine, LLC<br>14425 Bergen Blvd, Suite B<br>Noblesville, IN 46060<br>Office: 317.436.7801<br>Fax: 317.245.2518 |
| **Sponsor Contact:** | Andy Elsbury, President |
| **510(k) Contact:** | Karen E. Warden, PhD<br>BackRoads Consulting Inc.<br>PO Box 566<br>Chesterland, OH 44026<br>Office: 440.729.8457 |
| **Trade Name:** | STRUXXURE®-L and STRUXXURE®-A Plate System |
| **Common Name:** | Lateral and anterior lumbar plate system |
| **Regulatory Class:** | Class II |
| **Classification Name, Regulation, Product Code:** | Appliance, fixation, spinal intervertebral body, 888.3060, KWQ |
| **Device Description:** | The STRUXXURE®-L and STRUXXURE®-A Plate System is a lumbar plate and screw system. The implants are available in a variety of sizes to accommodate the individual anatomic and clinical circumstances of each patient. The implants are sold non-sterile. |
| **Intended Use:** | The STRUXXURE®-L and STRUXXURE®-A Plate System is indicated for treatment of spine instability via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the thoracic and thoracolumbar (T1-L5) spine or via an anterior surgical approach below the bifurcation of the great vessels in the lumbar and lumbosacral (L1-S1) spine. The indications for use include fracture (including dislocation and subluxation), tumor, degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, spondylolysis, spondylolisthesis, pseudarthrosis and failed previous spine surgery.<br>The STRUXXURE®-L System may also be attached to NEXXT MATRIXX® Lateral interbody devices. The STRUXXURE®-A Plate System may also be attached to NEXXT MATRIXX® ALIF interbody devices. In these configurations the STRUXXURE®-L and STRUXXURE®-A Plate System is used to treat skeletally mature patients having DDD at one or two contiguous levels from L2-S1 with up to Grade 1 spondylolisthesis or as an adjunct to fusion in patients diagnosed with degenerative scoliosis. |
| **Materials:** | The STRUXXURE®-L and STRUXXURE®-A Plate System is manufactured from titanium alloy as described by ASTM F136. |
| **Primary Predicate:** | CoreLink Lateral Plate System (CoreLink, LLC – K190016) |
| **Performance Data:** | Mechanical testing of the worst case STRUXXURE®-L and STRUXXURE®-A Plate System construct was performed according to ASTM F1717 and included static and dynamic compression and static torsion. In addition, screw backout testing and cage-plate dissociation testing were performed.<br>The mechanical test results demonstrate that the STRUXXURE®-L and STRUXXURE®-A Plate System performance is substantially equivalent. |

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| **Technological Characteristics:** | The STRUXXURE®-L and STRUXXURE®-A Plate System has the same technological characteristics as the predicate devices. These include basic design, material, method of stabilization and anatomic location. Therefore the fundamental scientific technology of the STRUXXURE®-L and STRUXXURE®-A Plate System is the same as previously cleared devices. |
| **Conclusion:** | The STRUXXURE®-L and STRUXXURE®-A Plate System possesses the same intended use and technological characteristics as the predicate devices. Therefore the STRUXXURE®-L and STRUXXURE®-A Plate System is substantially equivalent for its intended use. |