May 12, 2020

Back 2 Basics Direct, LLC
% Karen E. Warden, Ph.D.
President
BackRoads Consulting, Inc.
12520 Heath Road
Chesterland, Ohio 44026

Re: K192930
Trade/Device Name: Dymaxeon Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: April 10, 2020
Received: April 13, 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)*
K192930

Device Name
Dymaxeon Spine System

Indications for Use *(Describe)*

The Dymaxeon Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the non-cervical spine for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e., scoliosis, kyphosis, and/ or lordosis), trauma (i.e., fracture or dislocation), tumor, pseudarthrosis and/or failed previous fusion. The eCarbon rods can be used in the treatment of the above indications for use with the exception of procedures requiring instrumentation that spans more than 3-levels.

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:	26 February 2020
Sponsor:	Back 2 Basics Direct, LLC 6701 Rockside Road, Suite 200 Independence, OH 44131 Office: 216.447.5205 Fax: 216.447.6071
Sponsor Contact:	Louis Keppler MD, Principal
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	Dymaxeon Spine System
Common Name:	Posterior pedicle screw system
Device Classification:	Class II
Classification Names, Regulations, Product Codes:	Thoracolumbosacral pedicle screw system, 888.3070, NKB Spinal interlaminal fixation orthosis, 888.3050, KWP
Submission Purpose:	The subject 510(k) adds rod connectors and eCarbon rods to the Dymaxeon Spine System.
Device Description:	The Dymaxeon Spine System is a posterior pedicle screw system designed for temporary stabilization of the spine during the development of spinal fusion. The Dymaxeon Spine System is comprised of a variety of pedicle screws, rods, hooks, connectors and fasteners. The implants are sold sterile.
Indications for Use:	The Dymaxeon Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the non-cervical spine for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e., scoliosis, kyphosis, and/ or lordosis), trauma (i.e., fracture or dislocation), tumor, pseudarthrosis and/or failed previous fusion. The eCarbon rods can be used in the treatment of the above indications for use with the exception of procedures requiring instrumentation that spans more than 3-levels.
Materials:	eCarbon rods are manufactured from PEEK-OPTIMA Ultra Reinforced polymer (PEEK-OPTIMA per ASTM F2026 and carbon fibers). eCarbon rod integral markers are manufactured from gold wire (per ASTM B562). All other Dymaxeon Spine System components are manufactured from titanium alloy (Ti-6Al-4V ELI, per ASTM F136).
Primary Predicate:	Dymaxeon Spine System (Back 2 Basics Direct LLC – K170989)
Additional Predicates:	Dymaxeon Spine System (Back 2 Basics Direct LLC – K150184), Optima™ Spinal System (U&I Corporation – K051971), GII Osta-Pek® Plate (coLigne AG – K051089)

Performance Data:	Mechanical testing of the worst case Dymaxeon rod connector and eCarbon rod constructs included static and dynamic compression bending and static torsion according to ASTM F1717. In addition, axial and torsion grip testing was performed under ASTM F1798 on eCarbon rod subconstructs. The test results demonstrated equivalent mechanical performance of the Dymaxeon eCarbon rod and rod connectors compared to the cited predicate devices under the same test conditions.
Technological Characteristics:	The eCarbon rods of the Dymaxeon Spine System possess similar technological characteristics as one or more of the predicate devices. While the eCarbon rod is not identical to the predicate devices, the differences were shown not to raise new questions of safety and effectiveness. Therefore the fundamental scientific technology of the Dymaxeon Spine System is similar to previously cleared devices.
Conclusion:	The rod connectors and eCarbon rods of the Dymaxeon Spine System possess an intended use and technological characteristics similar to the predicate devices. Therefore these additional Dymaxeon Spine System components are substantially equivalent for their intended use.