**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 22, 2017

Back 2 Basics Direct, LLC
% Ms. Melissa Spang
Quality/Regulatory Specialist
JALEX Medical
30311 Clemens Road Suite #3D
Westlake, Ohio 44145

Re: K170989
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 21, 2017
Received: April 24, 2017

Dear Ms. Spang:

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 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K170989

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 in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1 - S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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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# 510(k) Summary


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| **Submitted by:** | Back 2 Basics Direct, LLC<br>6701 Rockside Road, Suite 200<br>Independence, OH 44131 |
| **Date:** | April 21, 2017 |
| **Contact Person:** | Melissa Spang, Quality/Regulatory Specialist |
| **Contact Telephone:** | (440) 541-0060 |
| **Contact Fax**: | (440) 933-7839 |


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|---|---|
| **Device Trade Name:** | Dymaxeon Spine System |
| **Device Classification Name:** | Thoracolumbosacral pedicle screw system |
| **Device Classification:** | Class II |
| **Reviewing Panel:** | Orthopedic |
| **Product Code:** | NKB, KWP |
| **Primary Predicate Device:** | Dymaxeon Spine System (K150184)<br>Additional predicate Dymaxeon Spine System (K121786)<br>Additional predicate Stryker Spine Xia III Spinal System (K071373)<br>There have been no recalls associated with these devices. |

**Device Description:**
The Dymaxeon Spine System is a posterior pedicle screw system manufactured from titanium alloy (Ti6A14V per ASTM F136) 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, and connectors. The Dymaxeon Spine System can be used for single or multiple level fixations.

The purpose of this submission is to obtain clearance for a modification to the tulip and mating set screws.

**Intended Use:**
The Dymaxeon Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1 - S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

**Mechanical Testing:**
Engineering rationale and non-clinical tests were performed to evaluate the thread change (axial grip testing per ASTM F1798).

**Substantial Equivalence:**
The modified Dymaxeon Spine System has the same intended use, indications for use, principles of operation, and technological characteristics of the predicate. Modifications do not raise new questions of

safety or effectiveness. Therefore, the modified Dymaxeon Spine System is substantially equivalent to the predicate.

**Conclusion:**
Back 2 Basics Direct, LLC concludes that the system is substantially equivalent to the predicate device.