September 26, 2019

Back 2 Basics Direct, LLC
% Karen Warden, PhD
President
BackRoads Consulting
12520 Heath Road
Chesterland, Ohio 44026

Re: K191537
Trade/Device Name: eCarbon IBDs
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: September 2, 2019
Received: September 4, 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 Ronald P. Jean, PhD
Director (Acting)
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)*

K191537

Device Name
eCarbon IBDs

Indications for Use *(Describe)*

The eCarbon-C is intended for anterior intervertebral body fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The eCarbon-C is indicated to treat cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at one level or two contiguous levels from C2 - T1. The eCarbon-C is to be used with supplemental fixation. The implants are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion.

The eCarbon-P is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) at one or two contiguous spinal levels from L2-S1. These patients should have had six months of nonoperative treatment. These patients may have had a previous non-fusion spinal surgery and/or may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). Additionally, the eCarbon-P can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The eCarbon-P is to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation indicated for lumbar spinal fusion procedures.

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:	7 June 2019
Sponsor:	Back 2 Basics Direct, LLC 6701 Rockside Road, Suite 200 Independence, OH 44131 Office: 216.447.5205 Fax: 216.447.6071
Sponsor Contact:	Scot Miller, DO, Principal
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	eCarbon IBDs (eCarbon-C and eCarbon-P)
Common Name:	Cervical and lumbar interbody fusion devices
Device Classification:	Class II
Regulation Names, Regulation Numbers, Product Codes:	Intervertebral fusion device with bone graft, 888.3080, cervical, ODP Intervertebral fusion device with bone graft, 888.3080, lumbar, MAX
Device Description:	The eCarbon IBDs are a collection of interbody devices. The cervical implants (eCarbon-C) have basic keystone shape in a columnar form while the lumbar devices (eCarbon-P) are essentially rectangular. All have a central cavity for bone graft and are offered in a variety of height, length, width and lordotic angulation combinations are available to accommodate the anatomic requirements of individual patients.
Indications for Use:	The eCarbon-C is intended for anterior intervertebral body fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The eCarbon-C is indicated to treat cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at one level or two contiguous levels from C2 - T1. The eCarbon-C is to be used with supplemental fixation. The implants are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion. The eCarbon-P is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) at one or two contiguous spinal levels from L2-S1. These patients should have had six months of nonoperative treatment. These patients may have had a previous non-fusion spinal surgery and/or may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). Additionally, the eCarbon-P can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The eCarbon-P is to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation indicated for lumbar spinal fusion procedures.
Materials:	The eCarbon IBDs are manufactured from PEEK-OPTIMA Ultra Reinforced polymer (PEEK-OPTIMA per ASTM F2026 and carbon fibers). Integral markers are manufactured from gold wire (per ASTM B562).
Primary Predicate:	Cascadia Interbody System (K2M Inc. – K160125)

Additional Predicates:	KIMBA® and KIMBA® Mini (SIGNUS Medizintechnik GmbH – K111792), MC+ (LDR Holding – K043479/K091088)
Performance Data:	Mechanical testing of the worst case eCarbon cervical implant included static and dynamic compression and static and dynamic torsion according to ASTM F2077. Mechanical testing of the worst case eCarbon lumbar implant included static and dynamic compression according to ASTM F2077. In addition, both worst case eCarbon implants were evaluated for subsidence according to ASTM F2267 and expulsion testing. The test results demonstrated equivalent mechanical performance of the eCarbon cervical and lumbar IBDs compared to the cited predicate devices under the same test conditions.
Technological Characteristics:	The eCarbon IBDs possess the same technological characteristics as one or more of the predicate devices. These include: • intended use (as described above) • basic design (structural column), • material (reinforced polymer) and • sizes (dimensions are comparable to those offered by the predicate systems) Therefore the fundamental scientific technology of the eCarbon IBDs is the same as previously cleared devices.
Conclusion:	The eCarbon IBDs possess the same intended use and technological characteristics as the predicate devices. Therefore the eCarbon IBDs are substantially equivalent for their intended use.