October 14, 2022

OC Medical Devices
% Karen E. Warden, Ph.D.
President
BackRoads Consulting Inc.
P.O. Box 566
Chesterland, Ohio 44026

Re: K221172
Trade/Device Name: FOCUS Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 14, 2022
Received: September 15, 2022

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,

Brent Showalter, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221172

Device Name

FOCUS Interbody System

Indications for Use *(Describe)*

The FOCUS Interbody System is intended to be used as a lumbar intervertebral fusion device at one or two adjacent levels from L2 to S1. This system should be limited to skeletally mature patients who have had six months of non-operative care for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. In addition, the FOCUS Interbody System can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The FOCUS Interbody System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate. These implants are intended for use with supplemental fixation indicated for lumbar spinal fusion procedures such as the OrthoCircle Spine Pedicle Screw System.

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:	14 September 2022
Sponsor:	OC Medical Devices 15 East Montgomery Crossroads, Suite 3 Savannah, GA 31406 888-463-5803
Sponsor Contact:	Jack Mathews, Quality/Operations Manager
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	FOCUS Interbody System
Common Name:	Lumbar interbody fusion device
Device Classification:	Class II
Regulation Names, Regulation Numbers, Product Codes:	Intervertebral fusion device with bone graft, lumbar, 888.3080, MAX
Device Description:	The FOCUS Interbody System includes interbody fusion devices for lumbar implantation. The FOCUS-T and FOCUS-TO implants are designed as structural columns to provide surgical stabilization of the lumbar spine. Each interbody has a central cavity to be packed with bone graft material and inferior/superior teeth to resist expulsion. Lateral windows provide for radiographic visualization on most implant sizes. The implants are available with and without the xCELLerate surface coating and in a variety of height, length, width and lordotic angulation combinations to accommodate the patient specific anatomy and clinical circumstances. The implants are supplied sterile.
Indications for Use:	The FOCUS Interbody System is intended to be used as a lumbar intervertebral fusion device at one or two adjacent levels from L2 to S1. This system should be limited to skeletally mature patients who have had six months of non-operative care for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. In addition, the FOCUS Interbody System can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The FOCUS Interbody System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate. These implants are intended for use with supplemental fixation indicated for lumbar spinal fusion procedures such as the OrthoCircle Spine Pedicle Screw System.
Materials:	The FOCUS Interbody System implants are manufactured from Ti6Al4V ELI titanium alloy (ASTM F136). The xCELLerate layered coating is manufactured from titanium powder (ASTM F1580) and calcium phosphate (ASTM F1185 and ASTM F1609). Instruments for implantation of the device are manufactured from stainless steel (under ASTM F899), some of which feature Radel (polyphenylsulfone) polymer handles.
Primary Predicate:	ShurFit 2C Lumbar Interbody Fusion System (Precision Spine Inc. – K212075)
Additional Predicate:	Cascadia™ Interbody System (K2M Inc. – K160547, K172009), K190959

Reference Device:	PCM® Cervical Disc System (NuVasive Inc. – P100012)
Performance Data:	Mechanical testing of the worst case FOCUS Interbody System implant included static and dynamic axial compression according to ASTM F2077 and subsidence according to ASTM F2267. The mechanical test results demonstrate that the FOCUS Interbody System performance is substantially equivalent to the predicate devices.
Technological Characteristics:	The FOCUS Interbody System possesses the many of the same technological characteristics as the predicate devices. These include basic design, material, method of stabilization, sizes and anatomic location: Differences between the subject and predicate devices included the substrate material (vs ShurFit 2C) and presence of coating (vs Cascadia™) but these did not raise new questions of safety and effectiveness. Therefore the fundamental scientific technology of the FOCUS Interbody System devices is similar to previously cleared devices.
Conclusion:	The FOCUS Interbody System possesses the same intended use and technological characteristics as the predicate devices. Therefore the FOCUS Interbody System is substantially equivalent for its intended use.