October 19, 2023

Acro Composites, LLC
% Karen Warden
President
BackRoads Consulting Inc.
PO Box 566
Chesterland, Ohio 44026

Re: K230478
Trade/Device Name: Acro Composites Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: August 29, 2023
Received: August 30, 2023

Dear Karen 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine D. Kavlock -S

for
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)*

K230478

Device Name

Acro Composites Interbody System

Indications for Use *(Describe)*

The Acro Composites Interbody System is intended for interbody fusion. The devices are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate to facilitate fusion and are to be used with supplemental fixation cleared for the implanted level.

The Acro Composites cervical devices are intended for anterior interbody fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The cervical devices are 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 multiple contiguous levels from C2-T1. The hyperlordotic implants ($\geq 10°$) are required to be used with an anterior cervical plate.

The Acro Composites lumbar devices are indicated for use at one or two contiguous levels in the lumbar spine from L2-S1, in skeletally mature patients who have had at least six months of non-operative treatment. The lumbar devices are indicated to treat lumbar 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 imaging studies (radiographs, CT, MRI). Additionally, the lumbar devices can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The hyperlordotic implants ($\geq 20°$) should be used with anterior supplemental fixation.

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:	21 February 2023
Sponsor:	Acro Composites, LLC 6950 W Snowville Road Brecksville, OH 44141
Sponsor Contact:	Mitchell Bass, President
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	Acro Composites Interbody System
Common Name:	Cervical and lumbar interbody fusion devices
Device Classification:	Class II
Regulation Name, Classification Number, Product Code:	Intervertebral fusion device with bone graft, cervical, 888.3080, ODP Intervertebral fusion device with bone graft, lumbar, 888.3080, MAX
Device Description:	The Acro Composites Interbody System includes interbody fusion devices for cervical and lumbar implantation manufactured from AcroPek – a carbon fiber reinforced PEKEKK polymer (CFRP) material. The implants are designed as a solid frame to provide surgical stabilization of the spine. Each interbody incorporates a central cavity that can be packed bone graft material. The implants are available in a variety of height, length, width and lordotic angulation combinations to accommodate the patient specific anatomy and clinical circumstances. The implants are sold sterile.
Indications for Use:	The Acro Composites Interbody System is intended for interbody fusion. The devices are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate to facilitate fusion and are to be used with supplemental fixation cleared for the implanted level. The Acro Composites cervical devices are intended for anterior interbody fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The cervical devices are 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 multiple contiguous levels from C2-T1. The hyperlordotic implants (≥ 10°) are required to be used with an anterior cervical plate. The Acro Composites lumbar devices are indicated for use at one or two contiguous levels in the lumbar spine from L2-S1, in skeletally mature patients who have had at least six months of non-operative treatment. The lumbar devices are indicated to treat lumbar 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 imaging studies (radiographs, CT, MRI). Additionally, the lumbar devices can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The hyperlordotic implants (≥ 20°) should be used with anterior supplemental fixation.

Materials:	The Acro Composites Interbody System implants are manufactured from PEKEKK resin (ASTM F1876) and carbon fiber filaments. Integral markers are manufactured from gold wire (per ASTM B562). The Acro Composites instruments are manufactured from medical grade stainless steel per ASTM F899; some of which include silicone handles.
Primary Predicate:	eCarbon IBDs (Back 2 Basics Direct, LLC – K191537)
Additional Predicates:	ostaPek Interbody Fusion Cages (coLigne, AG – K173148 & K181963), Cascadia Interbody System (K2M, Inc. – K160125 & K172009)
Performance Data:	Mechanical testing of the worst case Acro Composites Interbody System implants included static and dynamic axial compression, static and dynamic compression-shear, and static and dynamic torsion according to ASTM F2077. In addition, subsidence tests according to ASTM F2267 were performed. The mechanical test results demonstrate that the Acro Composites Interbody System performance is substantially equivalent to the predicate devices.
Technological Characteristics:	The Acro Composites Interbody System possesses the same technological characteristics as one or more of the predicate devices. These include: • basic design (structural column), • material (reinforced polymer) and • sizes (dimensions are comparable to those offered by the predicate systems)
Conclusion:	Therefore the fundamental scientific technology of the Acro Composites Interbody System is the same as previously cleared devices. The Acro Composites Interbody System possesses the same intended use and technological characteristics as the predicate devices. Therefore the Acro Composites Interbody System is substantially equivalent for its intended use.