Addivation Medical, LLC.
℅ Linda Braddon
President/CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

July 30, 2019

Re: K190291
Trade/Device Name: Addivation Medical Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: April 25, 2019
Received: May 1, 2019

Dear Linda Braddon:

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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*
K190291

Device Name
Addivation Medical Cervical Interbody System

Indications for Use *(Describe)*
The Addivation Medical Cervical Interbody System is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from the C2 to T1 disc.

DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy.

The Addivation Medical Cervical Interbody System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft, and is to be implanted via an open, anterior approach.

The Addivation Medical Cervical Interbody System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.

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 of Safety and Effectiveness

Date Summary Prepared	July 30, 2019
Sponsor	Addivation Medical, LLC 44 Riverdale Avenue Monmouth Beach, NJ 07750 Phone 908-910-1256
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 Phone 770-837-2681 Regulatory@SecureBME.com
Trade Name	***Addivation Medical Cervical Interbody System***
Common Name	Intervertebral body fusion device
Code – Classification	ODP 21 CFR 888.3080: Class II
Primary Predicate	K171496 Tritanium C Anterior Cervical Cage (Stryker)
Additional Predicate	K142152 CONSTRUX Mini PEEK Spacer System (ORTHOFIX)
Reference Predicate	K153207 Additive Orthopaedics Bone Wedge System
Device Description	The Addivation Medical Cervical Interbody System is a series of hollow, titanium interbody fusion cages intended for use in the cervical spine. The cage consists of an open window for bone graft containment and has serrations on the superior and inferior surfaces of the cage for fixation. The cage is offered in a variety of footprints, heights, and lordotic angles to adapt to varying patient anatomies. The Addivation Medical Cervical Interbody System implants are simultaneously built using Electron Beam Melting (EBM) method of additive manufacturing. Addivation Medical Cervical Interbody System Implants are provided sterile.
Indications for Use	The Addivation Medical Cervical Interbody System is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level or two contiguous levels from the C2 to T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have six weeks of non-operative therapy. The Addivation Medical Cervical Interbody System is to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft, and is to be implanted via an open, anterior approach. The Addivation Medical Cervical Interbody System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.

Technological Characteristics	The Addivation Medical Cervical Interbody System has the same technological characteristics as the predicate devices including the materials, design, function, range of sizes and intended use.
Performance Data	Non-clinical testing was performed to demonstrate the Addivation Medical *Cervical Interbody System* is substantially equivalent to other predicate devices in accordance with "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004 and Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, June 12, 2007. The following tests were performed: • Static and dynamic compression testing per ASTM F2077 • Static and dynamic torsion testing per ASTM F2077 • Subsidence testing per ASTM F2267 The results of these studies show the subject Addivation Medical *Cervical Interbody System* meets or exceeds the performance of the predicate devices, and the device was therefore found to be substantially equivalent.
Substantial Equivalence Summary (Conclusion)	Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject Addivation Medical *Cervical Interbody System* has been shown to be substantially equivalent to legally marketed predicate devices.