July 16, 2021

Additive Implants, Inc
℅ Karen Warden, PhD
President
BackRoads Consulting
12520 Heath Road
Chesterland, Ohio 44026

Re: K211111
Trade/Device Name: SureMAX-SA™ Cervical Standalone System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: June 11, 2021
Received: June 14, 2021

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
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)*

K211111

Device Name

SureMAX-SA™ Cervical Standalone System

Indications for Use *(Describe)*

The SureMAX-SA™ Cervical Standalone System is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients as an adjunct to fusion for the treatment of degenerative disc disease (DDD). DDD is defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment prior to treatment with the device. The SureMAX-SA™ Cervical Standalone System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. When used with the fixed or variable screws, the SureMAX-SA™ Cervical Standalone System is intended to be used at one or two levels from C2-T1 and requires no additional fixation. When used with one or more helical screws, the SureMAX-SA™ Cervical Standalone System is intended to be used at one level and with 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date:	9 June 2021
Sponsor:	Additive Implants, Inc. 3101 E. Shea Blvd, Suite 122 Phoenix, AZ 85028 Office: 602.795.8850 Fax: 602.595.7896
Sponsor Contact:	Jeff Horn, Vice-President of Commercialization
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	SureMAX-SA™ Cervical Standalone System
Common Name:	Interbody fusion system
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Intervertebral fusion device, 888.3080, OVE
Device Description:	The SureMAX-SA™ Cervical Standalone System is a collection of additively manufactured interbody spacers and integrated fixation for cervical implantation The cervical spacers have basic rounded rectangular shape and an open architecture. The integrated fixation consists of three screw options. A variety of height, length, width and anteroposterior angulation combinations are available to accommodate the anatomic requirements of individual patients. The SureMAX-SA™ Cervical Standalone System is provided sterile.
Indications for Use:	The SureMAX-SA™ Cervical Standalone System is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients as an adjunct to fusion for the treatment of degenerative disc disease (DDD). DDD is defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment prior to treatment with the device. The SureMAX-SA™ Cervical Standalone System is to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and implanted via an open, anterior approach. When used with the fixed or variable screws, the SureMAX-SA™ Cervical Standalone System is intended to be used at one or two levels from C2-T1 and requires no additional fixation. When used with one or more helical screws, the SureMAX-SA™ Cervical Standalone System is intended to be used at one level and with supplemental fixation..
Materials:	SureMAX-SA™ Cervical Standalone System interbody implants are manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F3001. The fixation screws and locking cam subcomponents are manufactured from Ti-6Al-4V ELI titanium alloy per F136.
Primary Predicate:	COALITION MIS™ Spacer, Globus Medical, Inc. – K151939
Additional Predicate:	Hexanium® ACIF, SpineVision SAS – K193000

Performance Data:	Mechanical testing of worst case SureMAX-SA™ Cervical Standalone System devices included subsidence, static and dynamic compression, static and dynamic compression shear and static and dynamic torsion according to ASTM F2267 and ASTM F2077. In addition, screw pushout properties were evaluated. The mechanical test results demonstrate that SureMAX-SA™ Cervical Standalone System performance is substantially equivalent to the predicate devices.
Technological Characteristics:	The SureMAX-SA™ Cervical Standalone System possesses the same technological characteristics as one or more of the predicate devices. These include: intended use (as described above), basic design (additively manufactured structure and integrated fixation), material (titanium alloy) and sizes (dimensions are comparable to those offered by the predicate systems). Therefore the fundamental scientific technology of the SureMAX-SA™ Cervical Standalone System is the same as previously cleared devices.
Conclusion:	The SureMAX-SA™ Cervical Standalone System possesses the same intended use and technological characteristics as the predicate devices. Therefore the SureMAX-SA™ Cervical Standalone System is substantially equivalent for its intended use.