January 3, 2020

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

Re: K193359
Trade/Device Name: SureMAX™ Family of Cervical Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 3, 2019
Received: December 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,

Brent L. Showalter, PhD
Assistant 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)*

K193359

Device Name
SureMAX™ Family of Cervical Spacers

Indications for Use *(Describe)*

The SureMAX™ Family of Cervical Spacers is intended for anterior intervertebral body fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The SureMAX™ Family of Cervical Spacers 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 multiple contiguous levels from C2 - T1. The SureMAX™ Family of Cervical Spacers is to be used with supplemental fixation; the hyperlordotic implants (≥10°) are required to be used with an anterior cervical plate. The implants are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion.

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:	3 December 2019
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™ Family of Cervical Spacers
Common Name:	Interbody fusion system
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Intervertebral fusion device with bone graft, cervical, 888.3080, ODP
Submission Purpose:	The subject 510(k) adds a new anterior cervical spacer (SureMAX™-X) to the SureMAX™ Family of Cervical Spacers.
Device Description:	The SureMAX™ Family of Cervical Spacers is an additively manufactured interbody system. These cervical implants have basic keystone shape and an open architecture. A variety of height, length, width and anteroposterior angulation combinations are available to accommodate the anatomic requirements of individual patients. The SureMAX™ Family of Cervical Spacers is provided sterile.
Indications for Use:	The SureMAX™ Family of Cervical Spacers is intended for anterior intervertebral body fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The SureMAX™ Family of Cervical Spacers 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 multiple contiguous levels from C2 - T1. The SureMAX™ Family of Cervical Spacers is to be used with supplemental fixation; the hyperlordotic implants (≥10°) are required to be used with an anterior cervical plate. The implants are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone to facilitate fusion.
Materials:	The SureMAX™ Family of Cervical Spacers is manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F3001, Grade 23).
Primary Predicate:	Cervical Spacer (Additive Implants, LLC – K182477)
Additional Predicates:	Cascadia Interbody System (K2M Inc. – K160125), Aleutian IBF System (K2M Inc. – K082698)
Performance Data:	The modified SureMAX™-X cervical spacer was evaluated via mechanical testing per ASTM F2077 (including static and dynamic compression and static and dynamic torsion), ASTM F2267 (subsidence) and expulsion. The results demonstrated the performance of the modified cervical spacer is substantially equivalent to the predicate.

Technological Characteristics:

The modified SureMAX™-X cervical spacer possesses the same technological characteristics as one or more of the predicate devices. These include:

- performance (as described above),
- basic design (additively manufactured structural interbody),
- material (titanium alloy) and
- size (dimensions are comparable to those offered by the cleared devices).

Therefore the fundamental scientific technology of the modified SureMAX™-X cervical spacer is the same as previously cleared devices.

Conclusion:

The modified SureMAX™-X cervical spacer possesses the same intended use and technological characteristics as the predicate devices. Therefore the modified SureMAX™-X cervical spacer is substantially equivalent for its intended use.