April 7, 2021

Blustone Synergy, LLC
% Christine Scifert
Partner
MRC Global, LLC
9085 E. Mineral Cir., Suite 110
Centennial, Colorado 80112

Re: K203520
Trade/Device Name: Blustone Synergy Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: February 5, 2021
Received: February 10, 2021

Dear Christine Scifert:

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 -S

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)*
K203520

Device Name
Blustone Synergy Slate Lavaflow System

Indications for Use *(Describe)*

The Blustone Synergy cervical (Slate Lavaflow) implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level or two contiguous levels from C2 to T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six weeks of non-operative treatment. The Blustone Synergy cervical implants are also to be used 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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K203520

Device Name
Blustone Synergy Lumbar Interbody Lavaflow System (Basalt LAVAFLOW, Magma LAVAFLOW, Obsidian LAVAFLOW)

Indications for Use *(Describe)*
The Blustone Synergy lumbar (Lavaflow) implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of non- operative therapy. Additionally, the Blustone Synergy lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The Blustone Synergy lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral 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)

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510(k) Summary
Blustone Synergy Interbody Fusion System
April 6, 2021

Company: Blustone Synergy, LLC.
5520 Ventana Ct.
Pueblo, CO 81005
Phone: (800) 232-9108

Company Contact: Tom Gentry
Admin Manager – Blustone Synergy, LLC
admin@blustonsynergy.com
760-992-6118

Official Correspondent: Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

Trade Name: Blustone Synergy Interbody Fusion System

Common Name: Intervertebral Fusion Device With Bone Graft, Cervical
Intervertebral Fusion Device With Bone Graft, Lumbar

Classification: Class II

Regulation Number: 21 CFR 888.3080 (Intervertebral body fusion device)

Panel: Orthopedic

Product Code: ODP, MAX

Device Description:
The Blustone Synergy Interbody Fusion System is composed of cervical and lumbar interbody fusion devices. The BluStone Synergy Slate Lavaflow System is a Titanium Plasma Coated cervical interbody fusion system comprised of parallel and 6° lordotic cages in two footprints with varying heights designed to accommodate patient anatomy, and may be implanted as a single device via an anterior approach. The Blustone Synergy Lumbar Interbody Lavaflow System is a Titanium Plasma Coated lumbar interbody fusion system comprised of various device configurations based on surgical approach and patient anatomy, and may be implanted via one of the following approaches: bi-laterally in pairs via a posterior (PLIF) approach; as a single device via a transverse (T-PLIF) approach; as a single device via a transforaminal (TLIF) approach; or as a single device via a lateral (LLIF) approach.

All Blustone Synergy Interbody Fusion System implant components are made of polyether-ether-ketone (Zeniva ZA-500 PEEK) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device.

This Traditional 510(k) submission seeks to expand the sizes offered for the MAGMA LLIF cages as well as add commercially pure (CP) titanium plasma coating per ASTM F1580 to the subject new MAGMA cages as well as all previously cleared cervical and lumber interbody fusion devices. Plasma-coated implant options will be denoted as the LAVAFLOW subfamily. Finally, this submission seeks to offer all implants as sterile devices via sterilization by ethylene oxide (EO) in addition to the previously cleared non-sterile, non-coated options.

Indications for Use:

BluStone Synergy Lumbar Interbody Lavaflow System (Basalt LAVAFLOW, Magma LAVAFLOW, Obsidian LAVAFLOW):

The Blustone Synergy lumbar (Lavaflow) implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have six months of non- operative therapy. Additionally, the Blustone Synergy lumbar implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The Blustone Synergy lumbar implants are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

BluStone Synergy Slate Lavaflow System:

The Blustone Synergy cervical (Slate Lavaflow) implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with cervical disc disease (DDD) at one level or two contiguous levels from C2 to T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six weeks of non-operative treatment. The Blustone Synergy cervical implants are also to be used with supplemental fixation.

Substantial Equivalence:

The subject Blustone Synergy Interbody Fusion System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Blustone Synergy Interbody Fusion (K171893; S.E. 09/08/2017)

Secondary Predicate:

- X-Spine Systems Inc. – Calix-C Cervical Interbody Spacer (K171075; S.E. 08/01/2017)
- X-Spine Systems Inc. – Calix Lumbar Spinal Implant System (K170119; S.E. 09/29/2017)

Reference devices:

- Titan Spine – Endoskeleton® TA (K080615; S.E. 06/17/2008)
- Elevation Spine – Elevation Spine Saber-C System (K190885; 08/07/2019)
- Curiteva, LLC. – Curiteva Lumbar Interbody Fusion System (K181589; 12/20/2018)

- Curiteva, LLC. – Curiteva Cervical Interbody Fusion System (K181261; 07/09/2018)

There are insignificant differences between the subject BluStone Synergy Interbody Fusion Lavaflow System and the predicates. The Indications for Use, Materials, and Geometry for predicate devices are all inclusive of the subject device. Testing shows that the subject BluStone Synergy Interbody Fusion Lavaflow System performs equivalent to the predicate BluStone Synergy Interbody Fusion System (K171893) and reference device Endoskeleton® TA (K080615). Additionally, an engineering rationale (included in the bench performance testing section) has been provided to demonstrate that the subject MAGMA small IBDs do not introduce a new worst case to the subject system. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Mechanical testing, including expulsion, dynamic compression per ASTM F2077, and wear debris analysis per ASTM F1877 have been performed on the subject Blustone Synergy cervical interbody devices and the results have shown them to be substantially equivalent to the predicate interbody devices.

Conclusion:

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.