Blustone Synergy
℅ Ms. Lisa Peterson
Official Correspondent
Blustone Synergy
5520 Ventana Ct.
Pueblo, Colorado 81005

Re: K171893

Trade/Device Name: Blustone Synergy Lumbar Interbody Fusion System Basalt, Magma, Obsidian), Blustone Synergy Cervical Interbody Fusion System (Slate)

Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: June 17, 2017
Received: June 26, 2017

Dear Ms. Peterson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Device Name
Blustone Synergy Lumbar Interbody Fusion System (Basalt, Magma, Obsidian), Blustone Synergy Cervical Interbody Fusion System (Slate)

Indications for Use (Describe)
Blustone Synergy lumbar implants (Basalt, Magma, Obsidian):
The Blustone Synergy lumbar 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 cervical implants (Slate):
The Blustone Synergy cervical (Slate) 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. 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)
510(k) Summary
Blustone Synergy Interbody Fusion System
Premarket Notification

SUBMITTED BY
Blustone Synergy
5520 Ventana Ct.
Pueblo CO 81005

CONTACT PERSON
Lisa Peterson
Kaedon Consulting, LLC
Phone: 512-507-0746
lpeterson@kaedonconsulting.com

DATE PREPARED
September 7, 2017

CLASSIFICATION NAME
Intervertebral Body Fusion Device with Bone Graft, Lumbar (MAX)
Intervertebral Body Fusion Device with Bone Graft, Cervical (ODP)

DEVICE CLASS
Class II

REGULATION NUMBER
888.3080 (Product Code MAX)
888.3080 (Product Code ODP)

COMMON NAME
Interbody Fusion Device

PROPRIETARY NAME
Blustone Synergy Lumbar Interbody Fusion System (Basalt, Magma, Obsidian)
Blustone Synergy Cervical Interbody Fusion System (Slate)

IDENTIFICATION OF PREDICATE DEVICE(S)
Predicate devices include various cleared interbody fusion systems:

Primary
- Eminent Spine: Eminent Spine Interbody Fusion System (K090064)

Additional
- DePuy Acromed: Lumbar I/F Cage (P960025)
- K2M, Inc: Aleutian System (K133614) and Cascadia System (K162264)
- Integrity Spine: Integrity Spine Lumbar Interbody Fusion System (K151819)
DEVELOPMENT

The Blustone Synergy Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of:

1) Blustone Synergy cervical interbody fusion device(s), which may be implanted as a single device via an anterior approach.

2) Blustone Synergy lumbar interbody fusion device(s), which may be implanted:
   - 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 lateral (LLIF) approach;
   - as a single device via a transforaminal (TLIF) approach

The Blustone Synergy 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. The System is implanted using a combination of device specific and universal class I instruments manufactured from stainless steel materials that conform to ASTM F899.

INDICATIONS

Blustone Synergy lumbar implants (Basalt, Magma, Obsidian):

The Blustone Synergy lumbar 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 cervical implants (Slate):

The Blustone Synergy cervical (Slate) 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. 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.

TECHNOLOGICAL COMPARISON TO PREDICATE(S)

The purpose of this premarket notification is to obtain clearance to market the Blustone Synergy Interbody Fusion System. The Blustone Synergy System implants were compared to the predicate devices identified above, and performance evaluation results, design features, materials and sizes were found to be substantially equivalent to these systems.
DISCUSSION OF NON-CLINICAL TESTING
The following non-clinical tests were conducted:
- Static and dynamic compression testing, conducted in accordance with ASTM F2077-14
- Static and dynamic torsion testing, conducted in accordance with ASTM F2077-14
- Subsidence testing, conducted in accordance with ASTM F2267-04(2011)
- Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02

CONCLUSIONS
The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. The non-clinical mechanical test results demonstrate that any minor differences do not impact device performance as compared to the predicates and demonstrate that the Blustone Synergy Interbody Fusion System is substantially equivalent to the predicate device.