December 21, 2017

Blustone Synergy
% Ms. Lisa Peterson
Principal Consultant
Kaedon Consulting LLC
14001 Hunters Pass
Austin, Texas 78734

Re: K172330
Trade/Device Name: Blustone Synergy Silica System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: October 30, 2017
Received: November 24, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K172330

Device Name
Blustone Synergy Silica System

Indications for Use *(Describe)*
The Blustone Synergy Silica System of implants is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The System is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. These devices are intended to be used with autograft or allograft bone.

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
Blustone Synergy Silica System
Premarket Notification

SUBMITTED BY	Blustone Synergy 5520 Ventana Ct. Pueblo CO 81005
ESTABLISHMENT REGISTRATION NUMBER	**Pending**
OWNER/OPERATOR NUMBER	**Pending**
CONTACT PERSON	Lisa Peterson Kaedon Consulting, LLC Phone: 512-507-0746 lpeterson@kaedonconsulting.com
DATE PREPARED	October 23, 2017
CLASSIFICATION NAME	Spinal Intervertebral Body Fixation Orthosis
DEVICE CLASS	Class II
REGULATION NUMBER	888.3060 (Product Code MQP)
COMMON NAME	Spinal Vertebral Body Replacement Device (MQP)
PROPRIETARY NAME	Blustone Synergy Silica System
IDENTIFICATION OF PREDICATE DEVICE(S)	Predicate devices include various cleared Vertebral Body Replacement systems: **Primary** - Eminent Spine: Eminent Spine Vertebral Body Replacement System (K090064)

DEVICE DESCRIPTION

The Blustone Synergy Silica System will be offered in parallel and lordotic device configurations of various heights to accommodate patient anatomy. The System of devices may be implanted in the thoracolumbar spine via an anterior approach.

The Blustone Synergy Silica 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

The Blustone Synergy Silica System of implants is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The System is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. These devices are intended to be used with autograft or allograft bone.

TECHNOLOGICAL COMPARISON TO PREDICATE(S)

The purpose of this premarket notification is to obtain clearance to market the Blustone Synergy Silica System. The Blustone Synergy Silica 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 Silica System is substantially equivalent to the predicate device.