July 23, 2021

Blustone Synergy, LLC
% Christine Scifert
Partner
MRC Global, LLC
9085 East Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K210382
Trade/Device Name: Blustone Synergy Diamond SA Cervical System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: July 17, 2021
Received: July 20, 2021

Dear Ms. 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 L. 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)*
K210382

Device Name
Blustone Synergy Diamond SA Cervical System

Indications for Use *(Describe)*
The Blustone Synergy Diamond SA Cervical System 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 degenerative disc disease (DDD) at one level or two contiguous levels from C2 to T1. Degenerative Disc Disease 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 Diamond SA Cervical System may be used with additional 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
Blustone Synergy Diamond SA Cervical System
21 July 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@blustonesynergy.com
760-992-6118

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

Trade Name: Blustone Synergy Diamond SA Cervical System

Common Name: Intervertebral Fusion Device With Integrated Fixation, Cervical

Classification: Class II

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

Panel: Orthopedic

Product Code: OVE

Device Description:
The BluStone Synergy Diamond Stand Alone (SA) Cervical System consists of the Diamond cervical interbody plate and screws to be used in conjunction with the Blustone Synergy Interbody Fusion SLATE cervical interbody fusion devices to form the Diamond Stand Alone Cervical System. The Diamond Stand Alone cervical system is designed to be used with allograft and/or autograft. Use of the Diamond SA Cervical System is intended to expedite the Anterior Cervical Device instrumentation procedure, while minimizing tissue disruption through a minimally invasive approach. The Diamond plate includes anterior nail spikes to resist rotation and two holes for insertion of the included bone screws as well as an integrated locking plate to resist bone screw backout. The Diamond cervical interbody plate and screws are manufactured from titanium alloy. Previously cleared SLATE cervical cages to be used with the Diamond plate and screws are manufactured from PEEK and include tantalum markers. All implant components are available in various sizes to accommodate varying patient anatomy.

Indications for Use:
The Blustone Synergy Diamond SA Cervical System 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 degenerative disc disease (DDD) at one level or two contiguous levels from C2 to T1. Degenerative Disc Disease 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 Diamond SA Cervical System may be used with additional supplemental fixation.

Substantial Equivalence:
The subject Blustone Synergy Diamond SA Cervical System is substantially equivalent to the following predicate devices:

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

Secondary Predicates:
- Globus Medical, Inc., COALITION™ Spacer (K083389, S.E. 03/26/2009; K131449, S.E. 07/30/2013; K173115,12/20/2017)
- Amendia, Inc. (Spinal Elements), Amendia Stand Alone Cervical System (K152972, S.E. 01/14/2016)
- Astura Medical, DOLOMITE Anterior Cervical Stabilization System (K202065, S.E. 10/26/2020)

There are insignificant differences between the subject Blustone Synergy Diamond SA Cervical 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 Diamond SA Cervical System performs equivalent to or better than the 5th percentile of FDA benchmark values . Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:
Bench performance testing was performed on the subject Diamond SA Cervical System implants including static and dynamic axial compression, static and dynamic axial compression shear, and static and dynamic torsion per ASTM F2077-18; subsidence per ASTM F2267-04 (2018); and expulsion.

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.