DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 16, 2016

Bone Solutions, Inc.
Mr. Drew Diaz
President - CEO
5712 Colleyville Blvd, Suite 210
Colleyville, Texas 76034

Re: K161568
Trade/Device Name: Bone Solutions Mixing and Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 31, 2016
Received: September 2, 2016

Dear Mr. Diaz:

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 Part 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 Parts 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 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 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 yours,

Christopher J. Ronk -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161568

Device Name
Bone Solutions Mixing and Delivery System

Indications for Use *(Describe)*
The Bone Solutions Mixing and Delivery System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5 510(k) Summary

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Bone Solutions, Inc. is hereby submitting this 510(k) summary.

Submitter [510(k) owner]

Bone Solutions, Inc.

5712 Colleyville Blvd., Suite 210

Colleyville, TX 76034

Company Contact

Drew Diaz
President-CEO
P 817.809.8850
diaz@bonesolutions.net

Submitted Device Information

Trade Name: Bone Solutions Mixing and Delivery System
Common Name: Piston Syringe
Classification Name: Syringe, Piston, General Hospital

Classification Information

Classification: Class II
Classification Regulation: 21 CFR 880.5860
Classification Product Code: FMF

Legally Marketed Predicate Devices

The Bone Solutions Mixing and Delivery System manufactured by Bone Solutions, Inc. (BSI) is substantially equivalent to the following device currently in commercial use:

Device:	ETEX Mixing and Delivery System
Manufacturer:	ETEX Corporation
Address:	675 Massachusetts Ave., 12th Floor, Cambridge, MA 02139
510(k) number:	K141245

Submitted Device Description

The ***Bone Solutions Mixing and Delivery System*** is comprised of a commercially available disposable medical piston syringe (syringe barrel with female luer, plunger) to facilitate mixing and delivery and a funnel to facilitate filling of the syringe barrel. The system will be offered with a 14 mL syringe barrel and will be provided empty.

Intended Use

The ***Bone Solutions Mixing and Delivery System****,* like the predicate, is intended to provide the surgeons with a means to mix and deliver graft material to an orthopedic surgical site.

The Bone Solutions Mixing and Delivery System is intended to be used in a controlled operating room environment with compatible devices by qualified medical personnel. The device is sterile, single use, with a 3 year expected shelf life.

Indications for Use:

The Bone Solutions Mixing and Delivery System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

Substantial Equivalence

The *Bone Solutions Mixing and Delivery System* is substantially equivalent to the predicate device, in which the basic features and intended uses are the same. The identical mixing syringes, made of identical materials, have been provided to both manufacturers by the same qualified supplier, as verified in the design history file. The lack of gradation markings on the BSI syringe does not change the performance or biocompatibility compared to the predicate Additions or deletions from the accessory tray are considered minor and do not raise questions concerning safety and effectiveness.

The ***Bone Solutions Mixing and Delivery System*** is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the ETEX Mixing and Delivery System, and raises no new issues of safety or effectiveness.

Drew Diaz
President-CEO
5712 Colleyville Blvd., Suite 210
Colleyville, TX 76034
P 817.809.8850

Date: August 31, 2016