February 18, 2020

Bone Solutions, Inc.
% Karen E. Warden, Ph.D.
President
BackRoads Consulting Incorporation
Po Box 566
12520 Heath Road
Chesterland, Ohio 44026

Re: K192674
Trade/Device Name: Mixing and Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: January 21, 2020
Received: January 23, 2020

Dear Dr. Warden:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192674

Device Name
Mixing and Delivery System

Indications for Use *(Describe)*

The 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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date:	11 February 2020
Sponsor:	Bone Solutions, Inc. 5712 Colleyville Blvd, STE 210 Colleyville, TX 76034
Sponsor Contact:	Drew Diaz, CEO Office: 817.809.8850 customerservice@bonesolutions.net
510(k) Contact:	Karen E. Warden, PhD President, BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457 info@followbackroads.com
Proposed Trade Name:	Mixing and Delivery System
Common Name:	Piston syringe
Device Classification:	Class II
Regulation Name, Regulation Number, Product Code:	Piston syringe, 880.5860, FMF
Submission Purpose:	To add auxiliary components to the cleared Bone Solutions Mixing and Delivery System components.
Device Description:	The Mixing and Delivery System is used to mix graft material such that it can be delivered to the patient. The system is comprised of the mixing/delivery syringe and auxiliary components including a threaded spindle with nut, open bore luer cap, pusher and cannulae which provide alternative methods of delivery for the mixed material.
Indications for Use:	The 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.
Primary Predicate:	Bone Solutions Mixing and Delivery System (Bone Solutions, Inc. – K161568)
Reference Devices:	InFill™ Graft Delivery System (Pinnacle Spine Group – K143488), ETEX Mixing and Delivery System (ETEX Corporation – K141245)
Performance Data:	The following non-clinical performance testing was performed to demonstrate the device performs as intended: Liquid and Air Leak Testing Separation from Axial Load Testing Disconnection Torsional Testing Sterility Validation Testing and Packaging Validation Testing The Mixing and Delivery System met all specified criteria and did not raise new safety or performance questions.
Substantial Equivalence Comparison:	The subject Mixing and Delivery System components possess the same indications for use and technological characteristics as the predicate devices and/or reference devices as shown below.

System ➔ Features🡻	Subject device: Bone Solutions Mixing and Delivery System K192674	Primary predicate: Bone Solutions Mixing and Delivery System K161568	Reference device: InFill™ Graft Delivery System K143488
Indications for Use:	The 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.	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.	The InFill™ Graft Delivery System is intended to be used for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site
Basic design	Piston syringe with auxiliary components	Piston syringe with auxiliary components	Piston syringe with auxiliary components
Material	Medical grade polymers	Medical grade polymers	Medical grade polymers
Principle of operation	Mix and deliver graft material	Mix and deliver graft material	Mix and deliver graft material
How supplied	Sterile, single use only	Sterile, single use only	Sterile, single use only
Syringe	Piston	Piston	Piston
Plunger	Axial push or helical screw	Axial push	Helical screw
Tip	Luer	Luer	Luer
Volume	14cc	14cc	14cc
Cannula	Luer & open bore threaded	-- NA --	Luer & open bore threaded
Length	100 & 150mm		150, 275 & 300mm
Diameter	4.3 & 8.0mm		3.5, 4.8 & 8.0mm
Accessories	Mixing plunger, funnel	Mixing plunger, funnel	Mixing plunger, funnel

Substantial Equivalence Conclusion:	Bone Solutions has demonstrated that the Mixing and Delivery System possesses the same intended use and technological characteristics as the predicate devices. Therefore the Mixing and Delivery System is substantially equivalent for its intended use.