July 28, 2019

Bonus Therapeutics Ltd.
Nir Shtayer
Head of Regulatory Affairs
Matam Advanced Technology Park, Building 8B
Haifa 3190501 Israel

Re: K190996
Trade/Device Name: Bonus Therapeutics Mixing and Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: April 17, 2019
Received: April 30, 2019

Dear Nir Shtayer:

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,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190996

Device Name
Bonus Therapeutics Mixing and Delivery System

Indications for Use *(Describe)*
The Bonus Therapeutics Mixing and Delivery System is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to surgical sites.

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.

510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter:	Bonus Therapeutics Ltd. Matam Advanced Technology Park, P.O.B 15143, Haifa, 3190501 ISRAEL
Date Prepared	April 8th, 2019
Contact:	Nir Shtayer Head of Regulatory Affairs Bonus Therapeutics Ltd Matam Advanced Technology Park, P.O.B 15143, Haifa, 3190501 ISRAEL Phone: 972-73-2067100 Fax: 972-73-2067111 Email: Nirsh@bonus-bio.com
Trade Name:	Bonus Therapeutics Mixing and Delivery System
Common Name:	Piston Syringe
Classification Name:	Piston Syringe, 21 CFR 880.5860
Regulatory Class:	II
Product Code:	FMF

Predicate Device:

ETEX Mixing and Delivery System, K141245

This predicate has not been subject to a design-related recall.

Reference Device:

InFill™ Graft Delivery System, K143488 is the reference device for the Cannula component of the Bonus Therapeutics Mixing and Delivery System.

This reference device has not been subject to a design-related recall.

Device Description:

The Bonus Therapeutics Mixing and Delivery System comprises a sterile piston syringe with an end cap, a cannulated applicator tip and a pusher rod. The syringe consists of syringe barrel with a plunger and an integrated mixing rod to enable mixing of the grafting material prior to application.

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The open bore barrel enables the loading of viscous grafting material by transferring it directly into the sterile syringe. The plunger sleeve is removable, and when removed it exposes the integrated mixing rod; a rotatable rod with four diagonal blades which allow mixing of the material as needed prior to injection, while maintained in the closed syringe barrel. When the plunger sleeve is attached, it operates as a simple piston to allow the extrusion of the material from the syringe.

The Cannula may be attached to the syringe via the Luer connection to facilitate the delivery of grafting material to the surgical site.

The Pusher may be used to release grafting material remaining in the Cannula.

The system is supplied sterile for single use.

Indications for Use:

The Bonus Therapeutics Mixing and Delivery System is intended to be used for the delivery of hydrated allograft, autograft or synthetic bone graft material to surgical sites.

This Indications for Use Statement for The Bonus Therapeutics Mixing and Delivery System is equivalent to the predicate device, as well as to the reference device.

Comparison of Technological Characteristics with the Predicate Device and the Reference Device:

The subject device has the same technological characteristics as the predicate and reference devices. The predicate device, as well as the reference device, use the same or very similar components as the subject device, and all are purchased by the 510(k) holders from the same supplier.

The differences that exist are limited to the cannula length and the presence of a pusher.

These differences have no significant effect on the performance, safety or effectiveness of the subject device.

Performance Data:

All necessary testing has been performed for the Bonus Therapeutics Mixing and Delivery System to assure that the device performs as intended.

Testing was performed on test units representative of the finished devices.

The device design was qualified through tests including:

- simulated use,
- liquid leak tests,
- piston friction,
- performance limits,
- biocompatibility evaluation,
- stability over shelf life.

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The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility:

The biocompatibility evaluation for the Bonus Therapeutics Mixing and Delivery System was conducted in accordance with the FDA guidance document 'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process": Guidance for Industry and Food and Drug Administration Staff', published June 16, 2016, and the International Standard ISO 10993-1:2009, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process', as recognized by FDA.

The battery of biocompatibility tests included:

- Cytotoxicity study
- Sensitization study – maximization
- Irritation study – intracutaneous reactivity
- Acute systemic toxicity
- Material-mediated pyrogenicity

Sterility:

The Bonus Therapeutics Mixing and Delivery System components are labeled as being sterile for single use, with a Sterility Assurance Level (SAL) of 10-6; sterilization is performed using Gamma radiation at 22.5 kGy. The sterilization process was validated according to AAMI ISO TIR 13004:2013 using the VD_{max} method, and a verification dose of 22.5 kGy.

Shelf life:

The components of the Bonus Therapeutics Mixing and Delivery System have a validated shelf life of 3 years. The ability of the sterile packaging to maintain a sterile barrier and device performance for this shelf life has been validated according to ISO 11607-1 by means of:

- Verification of package integrity (visual inspection, peel test and dye penetration test) following maximum dose sterilization and accelerated aging based on ASTM F1980.
- Verification of package integrity (as above) after completion of real time aging.
- Verification of device performance following accelerated aging and real time aging, including: visual inspection and bench tests in compliance with device specifications (liquid leakage, piston friction, performance limits and mixing rod torque resistance).

Mechanical performance bench testing:

The following tests were performed for the verification of the most important functional features of the devices on both newly manufactured devices and devices at different time points of their shelf life:

- Syringe tightness

- Piston friction
- Performance limit -cap closure
- Performance limit - clogged cannula attachment
- Mixing rod torque resistance

Conclusion:

The Bonus Therapeutics Mixing and Delivery System is substantially equivalent to the predicate device with regard to intended use, indications for use, and fundamental technology, including design, materials, sterility, and operational principles. Based on this information, the subject device does not raise any new issues regarding safety or efficacy when compared to the predicate device.