July 3, 2025

Bimed Teknik Aletler Sanayi & Ticaret A.S.
Aysel Kilic
Medical Quality Manager
Beylikduzu OSB Mah. Leylak Cd. No:16 Beylikduzu/Istanbul
Istanbul, 34520, Turkey

Re: K250733
Trade/Device Name: 3DOSE 1ml Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 4, 2025
Received: June 4, 2025

Dear Aysel Kilic:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250733

Device Name

3DOSE 1ml Syringe

Indications for Use *(Describe)*

The 3 DOSE 1 ml Syringe is intended for use by health care professionals for general purpose fluid aspiration/ injection.

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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K250733 510(k) SUMMARY

Contact Details

Applicant Name: Bimed Teknik Aletler Sanayi & Ticaret A.S.

Applicant Address: Beylikdüzü OSB Mah. Leylak Cd. No:16 Beylikdüzü/Istanbul Istanbul - 34520 Turkey

Applicant Contact Telephone: +90 0212 875 73

Applicant Contact: Mrs. Aysel Kilic

Applicant Contact Email: aysel.kilic@bimedteknik.com

Device Name

Device Trade Name: 3DOSE 1ml Syringe

Common Name: Piston syringe

Classification Name: Syringe, Piston

Regulation Number: 880.5860

Product Code: FMF

Predicate Device

Trade Name: TK Sterile Piston Syringe without Needle

510(k) Number: K191642

Classification Name: Syringe, Piston

Regulation Number: 880.5860

Product Code: FMF

Device Description Summary

The 3DOSE 1ml Syringe is a sterile, single-use, disposable and non-reusable manual syringe which is intended for injection of fluids into the body. The syringe can be used for pulling up any mixture, and after operating the locking handle for accurate dosing according to the ml/unit scale on the plunger.

The 3DOSE 1ml Syringe is used like a classic syringe, but includes a feature that provides tactile and audible feedback to the user during dosing.

Models: 3DOSE 1ml Syringe (125 GREEN)

3DOSE 1ml Syringe (100 ORANGE)

Material used:
1ml luer lock syringe : polypropylene
Syringe plunger-100-a: polyacetal
Syringe plunger-125-b: polyacetal
Syringe locking arm-orange: polyacetal
Syringe locking arm-green: polyacetal
Plastic part-a: polyacetal
Plastic part-b:polyacetal
Spring: stainless steel
Colours (white ym-by-107, blue mv-74542 (p.649 u), orange 3682, green yl-83030)

Intended Use/Indications for Use

The 3DOSE 1ml Syringe is intended for use by health care professionals for general purpose fluid aspiration/ injection.

Technological Comparison

Characteristic	**3DOSE 1ml Syringe K250733**	**TK Sterile Piston Syringes without Needle K191642**	**Discussion**
Common Name	Piston syringe	Piston syringe	Same – both devices are identified as piston syringes.
Classification Name	Syringe, Piston	Syringe, Piston	Same – both devices fall under the classification “Syringe, Piston.”
Product Code	FMF	FMF	Same – both devices share the product code FMF.
Classification	Class II	Class II	Same – both devices are classified as Class II.
Regulation Number	880.5860	880.5860	Same – both devices fall under regulation number 880.5860.
Indications for use	The 3DOSE 1ml Syringe is intended for use by health care professionals for general purpose fluid aspiration/ injection	TK Sterile Piston Syringe without Needle is intended for use by health care professionals for general purpose fluid aspiration/ injection.	Same-both devices are intended to be used by health care professionals for general fluid aspiration and injection
Operation Mode	For manual use only	For manual use only	Same – both devices are manually operated by the user.
Intended user	These syringes are intended for use by health care professionals.	These syringes are intended for use by health care professionals.	Same – both devices are intended to be used by trained health care professionals.
Syringe Volume	1 ml	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	Different - the subject device is only offered in 1 ml capacity. The limitation of capacity does not introduce new concerns and is evaluated for performance

Nozzle type	Luer Lock	Luer Slip and Luer Lock	Different – the nozzle type for the subject device only includes Luer Lock. The predicate device's nozzle type covers that of subject device. Therefore, the differences do not raise new questions about safety and effectiveness.
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same – both devices are sterilized using ethylene oxide (EO) sterilization method.
Shelf – life	5 years	5 years	Same – both devices have a validated shelf-life of 5 years.
Single Use	Yes	Yes	Same – both devices are intended for single use only.
Performance specifications	Complies with ISO 7886-1:2017 Sterile Hypodermic syringes for single use- Part 1: Syringes for manual use Complies with ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications-- Part 7: Connectors for intravascular or hypodermic applications Complies with ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications-- Part 20: Common test methods	- Complies with ISO 7886-1:2017 Sterile Hypodermic syringes for single use- Part 1: Syringes for manual use - Complies with ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications-- Part 7: Connectors for intravascular or hypodermic applications - Complies with ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications-- Part 20: Common test methods	Same – both devices comply with the applicable ISO standards for sterile hypodermic syringes and small-bore connector performance.
Configuration and material	Barrel - Polypropylene (PP) Plunger - Polyacetal Piston - Polyisoprene Rubber	Barrel - Polypropylene (PP) Plunger - Polypropylene (PP) Piston - Polyisoprene Rubber	Different – the materials of the plungers are different between the proposed device and predicate device. The biocompatibility test of the proposed device was conducted to demonstrate that the subject device is biocompatible. This difference does not raise any new safety and effectiveness questions.
Biocompatibility	The biocompatibility evaluation for the 3DOSE 1ml Syringe was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and the "Use of International Standard ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process". The syringe of testing included the following tests: Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Pyrogenicity Hemocompatibility	The biocompatibility evaluation for the TK Sterile Piston Syringe without needle was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and the "Use of International Standard ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process". The syringe of testing included the following tests: Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Pyrogenicity Hemocompatibility	Same – both devices were evaluated per ISO 10993 standards and passed the full panel of required biocompatibility tests.

Chemical properties	Chemical performances inspection are based on ISO 7886-1, inspection items are as follows: Limits for acidity or alkalinity, Limits for extractable metals. Results conform to ISO7886-1.	Chemical performances inspection are based on ISO 7886-1, inspection items are as follows: Limits for acidity or alkalinity, Limits for extractable metals. Results conform to ISO7886-1.	Same – both devices were evaluated for chemical properties per ISO 7886-1 and met the acceptance criteria.
Graduation lines and audible/tactile feature	The piston syringe is a device intended for medical purposes, consisting of a calibrated hollow barrel and a movable plunger. Additionally, there are extra parts to use the audible/tactile feature (locking arm, plastic part). There are graduation lines and teeth on the plunger.	The piston syringe is a device intended for medical purposes, consisting of a calibrated hollow barrel and a movable plunger.	Different – There are graduation lines on the barrel and piston. The extra parts integrated into the device enable the operation of the ratcheting dose mechanism, which provides both audible and tactile feedback to the user during injection. In addition, the additional audio notification feature of our device provides feedback to the user during the injection process and does not change the basic technological functionality and purpose of use of the device. In order to ensure the safety and effectiveness of the audio notification feature, in-process quality control tests were performed. These tests confirmed that the audio notification mechanism works correctly and does not have a negative effect on the overall performance of the device. For these reasons, it was concluded that our device is 'Substantially Equivalent' (SE) with the equivalent product in terms of safety and effectiveness.
Ratcheting Lock Mechanism	Included – the device contains a ratcheting lock mechanism to initiate injection and provide tactile/audible feedback.	Not included	Different – The subject device includes a locking arm and a plastic part not present in the predicate device. The locking arm is set to a “free” mode before drawing up the medicine, and once the syringe is filled, it is switched to “operation” mode, making the syringe ready for injection. The plastic part functions as a housing element, connecting the locking mechanism to the syringe body. This

			feature enhances ease of use but does not alter the fundamental operating principle of the device. It was evaluated through performance testing and determined not to raise new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Functional Performance Testing

ISO 7886-1

ISO 80369-7

Sterility

ISO 11135

ISO 11607-1

ISO 11607-2

ISO 10993-7

Biocompatibility Testing

ISO 10993-1

ISO 10993-4

ISO 10993-5

ISO 10993-10

ISO 10993-11

USP<788>

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the 3DOSE 1ml Syringe meet the established specifications necessary for safety and performance during its intended use. In addition, the collective bench testing demonstrates that the subject device does not raise different questions of safety or effectiveness when compared to the predicate device.

Conclusions:

The 3DOSE 1 ml Syringe is substantially equivalent to the TK Sterile Piston Syringe without Needle. The materials, performance, and operational features of both the subject device and the predicate device are substantially equivalent.