Set Medikal Sanayi Ve Ticaret Anonim Sirketi
% Mehmet Ormeci
Consultant
Medcer Uluslararasi Medikal Belgelendirme Anonim Sirketi
Taspinar Mahallesi 2800. Caddesi A-2 Apt. No:6 B/49
Ankara, 06830
Turkey

Re: K210200
Trade/Device Name: 1 ml Sterile Hypodermic Syringe For Single Use. With/Without Needle. Luer/Luer-Lock
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: April 7, 2021
Received: April 16, 2021

Dear Mehmet Ormeci:

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,

for Rumi Young
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210200

Device Name
Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock

Indications for Use *(Describe)*
The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

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.

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Special 510(k) Summary

510(k) Submitter Name	SET MEDIKAL SANAYI VE TICARET ANONIM SIRKETI
510(k) Submitter Address	Osmangazi Mahallesi Maresal Fevzi Cakmak Caddesi No:18 Esenyurt İstanbul/TURKEY
510(k) Submitter Telephone No	+90-212-622-0400
Primary Correspondent Contact Information	Mehmet Fatih Ormeci (Consultant) +90-532-397-3043 mformeci@gmail.com Fax Number: +90 (212) 689 4 828
Summary Preparation Date	05/12/2021

Trade or Proprietary Name	Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock
Common Name	Hypodermic Syringe
Classification Name	Piston Syringe
Regulation Number	21 CFR 880.5860
Product Code	FMF, FMI

	Subject Device Special 510k No	Predicate Device 510k No	Predicate Device Manufacturer
Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock	K210200/S002	K201284	SET MEDIKAL SANAYI VE TICARET ANONIM SIRKETI

Indications for Use:

The Sterile Hypodermic Syringe for Single use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

Syringe Size	Gauge	Length	Wall Type	Approval Number
1mL	21	5/8”	TW	K210200 Current Submission
	23	1”	TW	
	25	1”	RW	
2mL	20	1 1/2”	TW	K201284
	21	1 1/2”	TW	
		5/8”	TW	
	22	1 1/4”	TW	
	23	1 1/4”	TW	
		1”	TW	
	25	1”	RW	
	27	2”	RW	
		1 1/2”	RW	
2,5mL	21	1 1/2”	TW	K201284
		5/8”	TW	
	22	1 1/2”	TW	
		1 1/4”	TW	
	23	1 1/4”	TW	
		1”	TW	
	25	1”	RW	
	27	1 1/2”	RW	
		2”	RW	
3mL	21	1 1/2”	TW	K201284
		5/8	TW	
	22	1 1/4”	TW	
		1 1/2”	TW	
	23	1 1/4”	TW	
		1”	TW	
	25	1”	RW	
5mL	18	1 1/2”	TW	K201284
	20	1 1/2”	TW	
	21	1 1/2”	TW	
		5/8	TW	
	22	1 1/4”	TW	
		1 1/2”	TW	
	23	1 1/4”	TW	
		1”	TW	
	25	1”	RW	

Syringe Size	Gauge	Length	Wall Type	Approval Number
10 ml	18	1 1/2"	TW	K201284
	20	1 1/2"	TW	
	21	5/8"	TW	
		1 1/2"	TW	
	22	1 1/4"	TW	
		1 1/2"	TW	
	23	1”	TW	
		1 1/4"	TW	
20 ml	18	1 1/2"	TW	K201284
	20	1 1/2"	TW	
	21	5/8”	TW	
		1 1/2"	TW	
	22	1 1/4"	TW	
		1 1/2"	TW	
	23	1"	TW	
		1 1/4"	TW	
50 ml	15	1”	TW	K201284
	16	1”	TW	
	18	1 1/2"	TW	
	19	1 1/2"	TW	
	20	1 1/2"	TW	
	21	5/8"	TW	
		1 1/2"	TW	
	23	1 1/4"	TW	

Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock			
ITEM	**Legally Marketed Device / Predicate Device K201284**	**Modified Device (Adding New Size, 1ml)**	**Comparison**
Product name	Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock	Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock	Same
Product code	FMF	FMF	Same
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	Same
Class	II	II	Same
Indications for use	The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Same
Configuration	Piston Plunger Barrel	Piston Plunger Barrel	Same
Sterility condition	EO Sterilized	EO Sterilized	Same
Environment of use	Prescription use	Prescription use	Same
Intended users	Medical professionals and trained care givers	Medical professionals and trained care givers	Same
Single use	Yes	Yes	Same
Operation mode	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	Same
Label/labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Product performance	Complied with ISO 7886-1 ISO 7864 ISO 9626	Complied with ISO 7886-1 ISO 7864 ISO 9626	Same
Volume	2ml, 2,5ml, 3ml, 5ml, 6ml, 10ml, 12ml, 20ml, 24ml, 50ml	1ml	**Difference 1**
Sizes	14G,15G,16G,18G,19G,20G, 21G,22G,23G,24G,25G,26G,27G, 28G,29G,30G	21G, 23G, 25G	Same
Needle Lengths	4–50 mm	4–50 mm	Same

Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer-lock			
ITEM	**Legally Marketed Device / Predicate Device K201284**	**Modified Device (Adding New Size, 1ml)**	**Comparison**
Patient contact component and material			
Piston	Isoprene Rubber	Isoprene Rubber	Same
Barrel	PP	PP	Same
Plunger	PP/PE	PP/PE	Same
Needle	PP, SS304	PP, SUS304	Same
Sterilization			
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Device Description

1 ml Sterile Hypodermic Syringe is 3-piece design. These 3 pieces are piston, plunger and barrel. The piston is made from isoprene rubber. Barrel is made from polypropylene. Plunger is made from polypropylene and polyethylene combination. Needle is made from stainless steel 304 grade and hub of needle is made from polypropylene. There are with or without needle configurations within this Special 510k submission. There are luer and luer-lock configurations within this special 510k submission. This special 510k submission only covers the 1ml syringe but several needle dimensions including 21Gx5/8", 23Gx1", and 25Gx1". The barrel marking scale interval is 0.1 ml and legible for all configurations covered by this Special 510k submission. Luer and Luer-lock have a 6% conical design. The barrel is transparent. The length (without needle), outside diameter, inner diameter are 99.30/100.2mm, 6.9/6.75 and 4.70/4.70, respectively for luer and luer-lock configurations. Intended users are medical professionals and trained caregivers. It is prescription use only.

It is EtO sterile and a single use device. Packaging combination is maintained from a transparent sterilization film and Tyvek paper appropriate to EtO sterilization.

The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.

The products covered in this special 510k are in compliance with ISO 10993-1 and ISO 7886-1.

Product Name		**Sterile Hypodermic Syringe for Single use, with/without needle; luer/luer lock**	
Instructions for use		The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	
Volume		**1ml**	
Barrel Marking Specs (Scale interval)		0.1ml	
Tip type	Luer	✓	
	Luer lock	✓	
Configuration	Barrel, plunger	-	
	Piston, plunger, barrel	✓	
Barrel Transparency	Transparent	✓	
	UV Resistant	✓	
	Opaque	-	
Needle (Needle configurations are mentioned in the hypodermic needle product description table)		With or without needle	
Nozzle Type		Luer	Luer Lock
Length (without needle)		99.30	100.2
Diameter, Outside		6.90	6.75
Diameter, Inner		4.70	4.70
Plunger Material		PE	
Barrel Material		PP	
Piston Material		Isoprene rubber	
Nozzle Type		Luer, Luer lock, 6% conical, 1,2mm	
Lubricant Composition		Silicone	
Sterility Condition		EO sterilized	
Single Use		Yes	
Environment of use		Prescription Use	
Intended Users		Medical professionals and trained care givers	
Operation Mode		The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	
Graduation Legibility		Legible	
Endotoxin Limit		20 EU per device	
Biocompatibility		Complied with ISO 10993-4/5/10/11 (Cytotoxicity, Irritation, Sensitization Acute Systemic Toxicity, Hemolytical effect)	
SAL		10^{-6}	
Product Performance		Complied with ISO 7886-1	

Product Name	**Sterile Hypodermic needle for Single use**				
Sizes		21G		23G	25G
Needle Lengths (*): with 15 micron filter		5/8"		1"	1"
Needle Bond Strength		Min. 44N		Min. 34N	Min. 22N
Needle Cover Dimensions		8 ± 3		8 ± 3	8,31 x
Needle Cover Strength	Min. 2N – max. 20N				
Needle Cover Color	Transparent				
Needle Tip Configuration	Back bevel needle				
Configuration	Protective cap, Needle, Adhesives, Needle hub				
Sterility Condition	EO sterilized				
Single Use	Yes				
Environment of use	Prescription Use				
Intended Users	Medical professionals and trained care givers				
Operation Mode	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.				
Graduation Legibility	Legible				
Protective Cap Material	PP				
Adhesive Material	Epoxy resin				
Needle Hub Material	PP				
Needle Material	PP (hub and cover), SUS304 Stainless Steel				
Product Performance	Complied with ISO 7864, ISO 9626				
Endotoxin Limit	20 EU per device				
Biocompatibility	Complied with ISO 10993-4/5/10/11 (Cytotoxicity, Irritation, Sensitization Acute Systemic Toxicity, Hemolytical effect)				
SAL	10^{-6}				

Modification Discussion

In this Special 510(k) submission, a new size: 1ml syringe luer/luer lock with or without needle is covered. The intended use, raw material, manufacturing site, sterilization method, sterilization site, packaging material is same with cleared device K201284.

Performance Testing

The sterile, hypodermic syringe described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 9626 Second edition: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- ISO 7864:2016 Fourth Edition: Sterile hypodermic needles for single use — Requirements and test methods
- ISO 10993-4:2017 Biological Evaluation of Medical Devices — Part 4: Selection of Tests for Interactions with Blood
- ISO 10993-5:2009 Biological Evaluation of Medical Devices — Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices — Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Devices — Part 11: Tests for Systemic Toxicity

The sterile, hypodermic needle described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 9626 Second edition: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 7864:2016 Fourth Edition: Sterile hypodermic needles for single use — Requirements and test methods
- ISO 10993-4:2017 Biological Evaluation of Medical Devices — Part 4: Selection of Tests for Interactions with Blood

- ISO 10993-5:2009 Biological Evaluation of Medical Devices — Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices — Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Devices — Part 11: Tests for Systemic Toxicity

Conclusion

The differences between the cleared (predicate) and the modified device do not raise any new or different questions of safety or effectiveness since modified devices are tested in accordance with ISO 7886-1 standard. The subject devices are substantially equivalent to the predicate devices with respect to the indications for use, target populations, treatment method, and technological characteristics.