July 18, 2019

Terumo Corporation
℅ Rudima Jackson
Regulatory Affairs Specialist
Terumo Medical Corporation
265 Davidson Ave Suite 320
Somerset, New Jersey 08873

Re: K190427
Trade/Device Name: Immucise Intradermal Injection System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI, FMF
Dated: June 19, 2019
Received: June 20, 2019

Dear Rudima Jackson:

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,

Alan Stevens
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)*
K190427

Device Name
Immucise Intradermal Injection System

Indications for Use *(Describe)*
The Immucise Intradermal Injection System is indicated for intradermal injections of FDA approved drugs. The system is to be used in the deltoid region for infants aged two months (excluding low birth weight and/or preterm birth) to adults.

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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510(K) Summary: K190427

Manufacturer:	Kofu Factory of Terumo Corporation (510(k) applicant) Registration Number: 9681835
Address:	1727-1 Tsuijiarai, Showa-Cho Nakakoma-Gun, Yamanashi, Japan 409-3853
Corresponding official:	Rudima L Jackson Regulatory Affairs Specialist Terumo Medical Corporation
Telephone Number:	(732)302-4900
Email:	rudima.jackson@terumomedical.com
Summary Date:	July 8, 2019
Trade Name:	Immucise Intradermal Injection System
Common or Usual Name:	Intradermal Needle and Syringe
Regulation Number:	21 CFR 880.5570
Regulation Name:	Hypodermic Single Lumen Needle
Product Code:	FMI (Needle) and FMF (Syringe)
Class:	II
Panel:	General Hospital
Primary Predicate Device:	Immucise Intradermal Injection System, Manufactured by Kofu Factory of Terumo Corporation (Japan) (K181369)
Reference Device:	Intradermal Adapter, Manufactured by West Pharmaceutical Services, Inc. (K123588)

Device Description:

The Immucise Intradermal Injection System is a single use, electron beam radiation sterilized device that is designed to be used for intradermal injections of FDA approved drugs. This system consists of an Intradermal Injection Needle and an Immucise Syringe. The system is made of common materials used in needles and syringes. The Immucise Intradermal Injection Needle is comprised of a needle tube and a needle base. The Immucise Syringe is comprised of a barrel, a gasket and a plunger. The sterile Immucise Intradermal Injection Needle and Immucise Syringe are packed separately and assembled prior to use. The Immucise Intradermal Injection System is operated by a manual process.

Indications for Use:

The Immucise Intradermal Injection System is indicated for intradermal injections of FDA approved drugs. The system is to be used in the deltoid region for infants aged two months (excluding low birth weight and/or preterm birth) to adults.

Technological Characteristics:

The Immucise Intradermal Injection System with the pediatric indication is the same as its primary predicate device, K181369. The only change is the expanded indication to include infants aged two months (excluding low birth weight and/or preterm birth) to adults. Therefore, all technological characteristics are the exact same.

Summary of Comparative Information

This traditional 510(k) is being submitted for the Immucise Intradermal Injection System with the intent of expanding the indication to include infants aged two months (excluding low birth weight and/or preterm birth) to adults. The subject device is the same device as the primary predicate cleared under K181369 except for the Indications for Use. It has the same intended use, operating principle, design, construction, materials, and sterilization method. The proposed device also has the same design specification to the needle gauge, needle length, and syringe nominal capacity.

Summary of comparative information

Feature of the device	**Subject Device** **Immucise Intradermal Injection System**	**Primary Predicate (K181369) Immucise Intradermal Injection System**	**Reference Device (K123588) Intradermal Adapter**	**Discussion / Comment to Primary Predicate**
Product Code	FMI, FMF	FMI, FMF	FMF	Same as K181369
Classification	II	II	II	Same as K181369
Number of uses	Single use Rx only	Single use Rx only	Single use Rx only	Same as K181369

Materials	The subject device is constructed of materials commonly used in medical devices.
	
	Needle
	• Needle Tube
	  • Stainless steel cannula*
	  • Silicone oil lubricant*
	• Needle base
	  • Polypropylene hub*
		The subject device is constructed of materials commonly used in medical devices.
		
		Needle
		• Needle Tube
		  • Stainless steel cannula*
		  • Silicone oil lubricant*
		• Needle base
		  • Polypropylene hub*
			The West Pharmaceutical device is constructed of materials commonly used in medical devices.
			
			Adapter
			• Polycarbonate
				Same as K181369

	• Polypropylene luer lock connector* • Styrene-based TPE w/ pigment elastic spacer* • Polyacrylate needle hub adhesive **Syringe** • Barrel • Polypropylene barrel* • Silicone oil lubricant* • Black ink barrel printing • Gasket • Styrene-based TPE w/ pigment* • Silicone oil lubricant* • Plunger • Polystyrene *Patient body contacting material	• Polypropylene luer lock connector* • Styrene-based TPE w/ pigment elastic spacer* • Polyacrylate needle hub adhesive **Syringe** • Barrel • Polypropylene barrel* • Silicone oil lubricant* • Black ink barrel printing • Gasket • Styrene-based TPE w/ pigment* • Silicone oil lubricant* • Plunger • Polystyrene *Patient body contacting material		
Sterilization method	Electron Beam radiation	Electron Beam radiation	Ethylene Oxide	Same as K181369
Biocompatibility	Biocompatible The finished device's patient contacting parts were assessed in accordance with tests recommended in the FDA *Guidance - Use of International Standard ISO-10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."*	Biocompatible The finished device's patient contacting parts were assessed in accordance with tests recommended in the FDA *Guidance - Use of International Standard ISO-10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."*	Information not available	Same as K181369
Indications for Use	The Immucise Intradermal Injection System is indicated for use in intradermal injections of FDA approved drugs. The system is to be used in the deltoid region <u>for infants aged two months (excluding low birth weight and/or preterm birth) to adults.</u>	The Immucise Intradermal Injection System is indicated for use in intradermal injections of FDA approved drugs. The system is to be used in the deltoid region for adults.	The Intradermal Adapter is an accessory to a 1 ml, ½ inch fixed-needle allergy syringe indicated for use as a guide for performing intradermal injections.	The proposed indications for use for the subject device have been modified to include a specific user population (pediatric) to the primary predicate. The differences in the indications does not create

				a new intended use. As the intended use in the subject and predicate devices has not changed, the modification to the indications for use does not raise different questions of safety and effectiveness.
Operating principles	**Manual**	**Manual**	**Manual**	Same as K181369
Design specifications	**Needle Gauge** 33G (0.2 mm) **Needle Length** 1.15 mm **Syringe Nominal Capacity** 0.4 mL	**Needle Gauge** 33G (0.2 mm) **Needle Length** 1.15 mm **Syringe Nominal Capacity** 0.4 mL	**Adapter** Designed to adapt to a disposable 1cc piston syringe with needle (1 ml of capacity, 1/2" needle length, 27 – 29G needle gauge).	Same as K181369
Package (Primary)	**Needle** Individual package **Syringe** Blister package	**Needle** Individual package **Syringe** Blister package	**Adapter** Blister package	Same as K181369
Shelf life	**Needle**: 36 months **Syringe**: 12 months	**Needle**: 36 months **Syringe**: 12 months	Information not available	Same as K181369

Performance Data:

Bench Test

Bench testing for Immucise Intradermal Injection System was performed in K181369 using non-aged and aged samples and met the predetermined acceptance criteria. No additional bench tests were deemed necessary to support the expanded indication, since the subject device is identical to the primary predicate K181369.

Animal Test

Terumo conducted an animal study to demonstrate the intended use of intradermal injection for adults in K181369. In order to expand the indications for use from adults only to infants (aged two months) to adults, Terumo conducted an additional animal study. The test method and acceptance criteria are same as the study performed previously except for the skin thickness.

Summary of animal test

Test Name	Test Description / Standard
Animal study (Functionality test)	In-house standard: This study was conducted to evaluate the efficacy of Immucise Intradermal Injection System for the indication for use. The test compared the post-injection wheal formation success rate between the Immucise Intradermal Injection System and the reference device of West Intradermal Adapter.
Animal study (Histopathological evaluation)	In-house standard: This study was conducted to validate the injection depth required for the indications for use.

Based on these animal studies, Terumo concludes that the Immucise Intradermal Injection System has been found to be substantially equivalent for the intended use and for the target patient population without raising different questions of safety and effectiveness. The test results support a determination of substantial equivalence.

Conclusion:

In summary, the intended use, technology/principle of operation, materials, and performance showed that the subject device did not raise different questions of safety and effectiveness when compared to the predicate devices. Therefore, Immucise Intradermal Injection System is substantially equivalent to the legally marketed Predicate Device.