November 13, 2018

Terumo Corporation
Phebe Varghese
Sr. Regulatory Affairs Specialist
265 Davidson Ave., Suite 320
Somerset, New Jersey 08873

Re: K181369
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: October 10, 2018
Received: October 11, 2018

Dear Phebe Varghese:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181369

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 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.

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SECTION 5 – 510(K) SUMMARY

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92.

A. SUBMITTER INFORMATION (807.92(a)(1))

Prepared by: Phebe Varghese
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Prepared for: ***Owner/Operator***
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Date prepared: November 9, 2018

B. DEVICE NAME (807.92(a)(2))

Proprietary Name:	Immucise Intradermal Injection System
Common Name:	Intradermal Needle and Syringe
Classification Name:	Hypodermic Single Lumen Needle and Piston Syringe
Classification Panel:	General Hospital and Personal Use Therapeutic Devices
Regulation:	21 CFR 880.5570
Product Code:	FMI (Needle) and FMF (Syringe)
Classification:	Class II

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed devices to which substantial equivalences are claimed are:

K052034 – Terumo Syringe with/without Needle, manufactured by Terumo (Philippines) Corporation – Primary Predicate

K123588 – Intradermal Adapter manufactured by West Pharmaceutical Services, Inc.

Note: Terumo Corporation has established the K052034 Terumo Syringe/Needle as the primary predicate.

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted for the Immucise Intradermal Injection System, manufactured by Kofu Factory of Terumo Corporation, for the purposes of establishing substantial equivalence to a legally marketed predicate device.

E. DEVICE DESCRIPTION (807.92(a)(4))

Principle of Operation Technology

The Immucise Intradermal Injection System is operated by manual process.

Design/Construction

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. The system consists of a needle and syringe that are packed separately and assembled prior to use. The Immucise Intradermal Injection Needle consists of a needle tube and needle base, and the Immucise Syringe consists of a barrel, gasket and plunger.

Materials

The materials for the Immucise Intradermal Injection System are provided in the tables below.

Table 5.1: List of Materials of the Immucise Intradermal Injection Needle

Part Name		Material
Needle Tube	Cannula*	Stainless Steel
	Needle Lubricant*	Silicone Oil
Needle Base	Needle Hub*	Polypropylene
	Luer Lock Connector*	Polypropylene
	Elastic Spacer*	Styrene-based Thermoplastic Elastomers containing Pigment
	Needle Hub Adhesive	Polyacrylate
Individual Package	Protector	Polypropylene
	Seal Film	Paper

*Materials that contact patient's body directly or indirectly *via* injection formulation.

Table 5.2: List of Materials of the Immucise Syringe

Part Name		Material
Barrel	Barrel*	Polypropylene
	Barrel Lubricant*	Silicone Oil
	Barrel Printing	Black Ink
Piston	Gasket (Plunger stopper) *	Styrene-based Thermoplastic Elastomers Containing Pigment
	Gasket Lubricant*	Silicone Oil
	Plunger	Polystyrene
Individual Package	Top Film	PET - PE - PE Film (Polyethylene terephthalate - Polyethylene - Polyethylene)
	Bottom Film	LDPE+AB - Ionomer - L-LDPE - LDPE+AB (Low Density Polyethylene + Acrylonitrile Butadiene - Linear Low-Density Polyethylene - Low Density Polyethylene + Acrylonitrile Butadiene)

*Materials that contact patients' body directly or indirectly *via* injection formulation.

Specifications

The specifications for the Immucise Intradermal Injection System are provided in the table, below.

Table 5.3: Immucise Intradermal Injection System Specifications

Part	Specification
Needle Gauge	33 G (0.2 mm)
Needle Length	1.15 ± 0.10 mm
Syringe Nominal Capacity	0.4 mL

F. INDICATIONS FOR USE (807.92(a)(5))

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 adults.

Note: The proposed indications for use for the subject device has been modified to include a specific user population and injection site. This differences in the indications for use between the subject device and the predicate devices (K052034 and K123588) does not create a new intended use. Since the intended use between the subject and predicate devices remain unchanged, the differences in indications for use does not raise different questions of safety and effectiveness.

G. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

The Immucise Intradermal Injection System, the subject of this 510(k), is substantially equivalent in its intended use, technology/principles of operation, materials, and performance to:

K052034 – Terumo Syringe with/without Needle, manufactured by Terumo (Philippines) Corporation – Primary Predicate.

K123588 – Intradermal Adapter manufactured by West Pharmaceutical Services, Inc.

A comparison of the technological characteristics is summarized in the table, below.

Table 5.4: Summary of Comparative Information

Device Characteristics	Subject Device: Immucise Intradermal Injection System	Primary Predicate Device: K052034 TERUMO Syringe with/without Needle	Predicate Device #2: K123588 Intradermal Adapter
Manufacturer	Kofu Factory of Terumo Corporation (Japan)	Terumo (Philippines) Corporation	West Pharmaceutical Services, Inc.
Product Code	FMI, FMF	FMI, FMF	FMF
Intended Use/ 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 adults.	The Terumo Syringe with/without needle is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.	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.
Operation Principle	Manual	Manual	Manual
Design and Construction	**Needle and Syringe** Collectively, the "system" is designed to facilitate intradermal injections of fluids and formulations that have been deemed acceptable for injection. **Needle** Consists of needle tube and needle base - and features a design controlling depth and angle of needle insertion into the dermis. **Syringe** Consists of barrel, gasket and plunger.	**Needle and Syringe** Collectively, the needle and syringe are designed to facilitate injection of fluids to the body and can be used to withdraw fluid from the body. **Syringe <u>with</u> Needle** Consists of needle tube, needle hub, barrel, gasket and plunger.	**Adapter** Designed to be attached to a 1cc syringe with needle to control the depth and angle of needle insertion into dermis. **Adapter** A single component that is designed for attachment to a syringe for subsequent delivery of fluid into the dermis.

Device Characteristics	Subject Device: Immucise Intradermal Injection System	Primary Predicate Device: K052034 TERUMO Syringe with/without Needle	Predicate Device #2: K123588 Intradermal Adapter

Components 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*
	  •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
		The predicate Terumo device is constructed of materials commonly used in medical devices.
		
		Needle:
		• Needle Tube
		  •Stainless steel cannula*
		  •Silicone oil lubricant*
		
		• Needle hub
		  •Polypropylene hub*
		  •Epoxy 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
			The West Pharmaceutical device is constructed of materials commonly used in medical devices.
			
			Adapter
			• Polycarbonate

Device Characteristics	Subject Device: Immucise Intradermal Injection System	Primary Predicate Device: K052034 TERUMO Syringe with/without Needle	Predicate Device #2: K123588 Intradermal Adapter
Specifications	**Needle Gauge**: 33 G (0.2 mm) **Needle Length**: 1.15 mm **Syringe Nominal Capacity:** 0.4 mL	**Needle Gauge:** 23 - 27 G (0.4 – 0.65 mm) **Needle Length:** 3/8"-1/2" (10 - 12 mm) **Syringe Nominal Capacity:** 1mL	**Adapter:** Specified/designed to adapt to a disposable 1cc piston syringe with needle (1 ml of capacity, 1/2" needle length, 27 – 29 G needle gauge).
Package (Primary)	**Needle**: Individual package **Syringe:** Blister package	**Syringe w/wo Needle:** Blister Package	**Adapter:** Blister Package
Sterilization	Electron Beam radiation	Electron Beam radiation	Ethylene Oxide
Shelf life	**Needle**: 36 months **Syringe**: 12 months	60 months	Information not available

Substantial Equivalence Discussion

The Immucise Intradermal Injection System (subject device) and Terumo Syringe with/without Needle (predicate device – K052034) have the same intended use, operating principle, basic design, construction, materials, and sterilization method. The proposed device has a modified design specification to the needle gauge, needle length, and syringe nominal capacity. The differences between the subject device and K052034 have been evaluated through bench and human factors and usability engineering studies, and test results concluded that the differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

The Immucise Intradermal Injection System (subject device) and Intradermal Adapter (predicate device – K123588) have the same intended use and operating principle and a similar design and construction. The proposed device has differences in design specification, materials, and sterilization method. The differences between the subject device and K123588 have been evaluated through bench and animal testing, and test results concluded that the differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

H. NON CLINICAL TESTS (807.92(b)(1))

Performance Testing

Bench Testing

Performance testing (Bench) was conducted to ensure that the Immucise Intradermal Injection System met the applicable design and performance requirements throughout its shelf life, verify conformity to the applicable external and internal standards and FDA guidance[1], and demonstrate substantial equivalence to the predicate devices. The following bench tests were performed on the Immucise Intradermal Injection System.

Table 5.5: Summary of Bench Test (Immucise Intradermal Injection Needle)

Test	Standard
Cleanliness	ISO 7864:2016 Section 4.3
Limits for acidity or alkalinity	ISO 7864:2016 Section 4.4
Limits for extractable metals	ISO 7864:2016 Section 4.5
Positive pressure liquid leakage	ISO 7864:2016 Section 4.8.1 ISO 80369-7:2016 Section 6.1
Sub-atmospheric pressure air leakage	ISO 7864:2016 Section 4.8.1 ISO 80369-7:2016 Section 6.2
Stress cracking	ISO 7864:2016 Section 4.8.1 ISO 80369-7:2016 Section 6.3
Resistance to separation from axial load	ISO 7864:2016 Section 4.8.1 ISO 80369-7:2016 Section 6.4
Resistance to separation from unscrewing	ISO 7864:2016 Section 4.8.1 ISO 80369-7:2016 Section 6.5
Resistance to overriding	ISO 7864:2016 Section 4.8.1 ISO 80369-7:2016 Section 6.6
Surface finish and visual appearance (Needle tube)	ISO 7864:2016 Section 4.10.1 ISO 9626:2016 Section 5.2
Cleanliness (Needle tube)	ISO 7864:2016 Section 4.10.1 ISO 9626:2016 Section 5.3
Limits for acidity and alkalinity (Needle tube)	ISO 7864:2016 Section 4.10.1 ISO 9626:2016 Section 5.4
Dimensions (Needle tube)	ISO 7864:2016 Section 4.10.1 ISO 9626:2016 Section 5.6

[1] Guidance on the Content of Premarket Notification [510(K)] Submissions for Hypodermic Single Lumen Needles and Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes

Test	Standard
Stiffness (Needle tube)	ISO 7864:2016 Section 4.10.1 ISO 9626:2016 Section 5.8
Resistance to breakage (Needle tube)	ISO 7864:2016 Section 4.10.1 ISO 9626:2016 Section 5.9
Resistance to corrosion (Needle tube)	ISO 7864:2016 Section 4.10.1 ISO 9626:2016 Section 5.10
Freedom from defects	ISO 7864:2016 Section 4.10.3
Lubricant	ISO 7864:2016 Section 4.10.4
Needle point	ISO 7864:2016 Section 4.11
Bond between hub and needle tube	ISO 7864:2016 Section 4.12
Patency of lumen	ISO 7864:2016 Section 4.13
Needle length	In-house Standard
Bevel length	In-house Standard
Needle hub strength	In-house Standard
Dead volume	In-house Standard

Table 5.6: Summary of Bench Test (Immucise Syringe)

Test	Standard
General	ISO 7886-1:2017 Section 6.1
Limits for acidity or alkalinity	ISO 7886-1:2017 Section 6.2
Limits for extractable metals	ISO 7886-1:2017 Section 6.3
Lubricant (visual inspection)	ISO 7886-1:2017 Section 7
Lubricant (quantity)	ISO 7886-1:2017 Section 7
Tolerance on graduated capacity	ISO 7886-1:2017 Section 8
Barrel (rotation of flange)	ISO 7886-1:2017 Section 10
Barrel (visual inspection of flange)	ISO 7886-1:2017 Section 10
Plunger stopper /plunger assembly (Detachment of plunger stopper from plunger)	ISO 7886-1:2017 Section 11
Piston /plunger assembly (Distance between plunger and flange)	ISO 7886-1:2017 Section 11
Nozzle	ISO 7886-1:2017 Section 12.1 ISO 80369-7:2016 Section 5

Test	Standard
Positive pressure liquid leakage	ISO 7886-1:2017 Section 12.1 ISO 80369-7:2016 Section 6.1
Sub-atmospheric pressure air leakage	ISO 7886-1:2017 Section 12.1 ISO 80369-7:2016 Section 6.2
Stress cracking	ISO 7886-1:2017 Section 12.1 ISO 80369-7:2016 Section 6.3
Resistance to separation from axial load	ISO 7886-1:2017 Section 12.1 ISO 80369-7:2016 Section 6.4
Resistance to separation from unscrewing	ISO 7886-1:2017 Section 12.1 ISO 80369-7:2016 Section 6.5
Resistance to overriding	ISO 7886-1:2017 Section 12.1 ISO 80369-7:2016 Section 6.6
Dead Space	ISO 7886-1:2017 Section 13.1
Freedom from air leakage past piston	ISO 7886-1:2017 Section 13.2
Freedom from liquid leakage past piston	ISO 7886-1:2017 Section 13.2
Force to operate the piston	ISO 7886-1:2017 Section 13.3
Fit of plunger stopper/plunger in barrel	ISO 7886-1:2017 Section 13.4
Sliding resistance	In-house Standard (verified requirements of ISO 7886-1:2017 Section 11)
Stopper force	In-house Standard (verified requirements of ISO 7886-1:2017 Section 11)

Table 5.7: Summary of Bench Test (Immucise Intradermal Injection System)

Test	Standard
Drug flowability	In-house Standard
Pressure resistance	In-house Standard
Particulate matter	USP 788

Bench testing met the predetermined acceptance criteria, and results support a determination of substantial equivalence.

Animal Study

Terumo conducted the animal study to evaluate the intended purpose of intradermal injection in a simulated use condition. The functionality test compared the post-injection wheal formation success rate between the Immucise Intradermal Injection System and West Intradermal Adapter. The test demonstrated the substantial equivalency to the predicate, and the histopathological evaluation validated the injection depth required for the intended use. Animal testing met the predetermined acceptance criteria, and results support a determination of substantial equivalence.

Human Factors and Usability Engineering Study

Terumo conducted the human factors and usability engineering study to evaluate the user interface with the Immucise Intradermal Injection System in accordance with the FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices," issued on February 3, 2016, and to ensure the design of the system does not result in use-errors that may cause serious harm. The testing resulted in no use errors that may cause serious harm. Therefore, Terumo believes that based on the design validation test, the whole device specification is substantially equivalent to the predicates in human factors and usability aspect, including user interface.

In summary, performance test (Bench, Animal, and Human Factors and Usability Engineering studies) results support a determination of substantial equivalence to the predicate devices.

Biocompatibility

In accordance with ISO 10993-1, the Immucise Intradermal Injection System is classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (<24 hours).

The finished device's patient contacting parts were assessed in accordance with tests recommended in the FDA *Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO-10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."*
Screening tests were performed on devices subjected to appropriate simulated aging

to demonstrate that an acceptable biocompatibility profile is maintained throughout the shelf life of the product. The table below provides a list of biocompatibility tests conducted on the Immucise Intradermal Injection System.

Table 5.8: Summary of ISO 10993 Biocompatibility Testing on Immucise Intradermal Injection System (Needle and Syringe)

Non-aged, Sterile, Finished Device
Cytotoxicity
Sensitization
Intracutaneous Reactivity
Acute Systemic Toxicity
Pyrogenicity
Hemolysis (Indirect Contact)
Physicochemical Profile: Physicochemical and FT-IR
Accelerated Aged, Sterile, Finished Device
Cytotoxicity
Hemolysis (Indirect Contact)
Physicochemical Profile: Physicochemical and FT-IR

Additionally, Terumo conducted particulate matter test in accordance with USP <788> Particulate Matter in Injections, and the test met the USP acceptance criteria.

Results of the testing demonstrated that the device is biocompatible throughout the product's shelf life.

Sterilization

The Immucise Intradermal Injection System is sterilized via electron beam radiation. The sterility of the device is assured using a sterilization method validated in accordance with ISO11137-1 First edition: 2006-04-15 *Sterilization Of Health Care Products – Radiation – Part 1: Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices* and ISO 11137-2 Third edition: 2013-06-01 *Sterilization Of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose to provide a Sterility Assurance Level (SAL) of* 10^{-6} to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Packaging

Package integrity testing, after environmental conditioning and simulated transportation in accordance with ISTA 3A, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.

I. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests. However, data from a publication (Laurent A. et al.[2]) was used as evidence to support the needle length and tolerance of the Immucise Intradermal Injection System. The data from the publication showed that the differences in technological characteristics of the subject device did not raise different questions of safety, when compared to the predicate devices.

J. CONCLUSION (807.92(b)(3))

In summary, the Immucise Intradermal Injection System, subject of this 510(k), is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the following predicates:

K052034 – Terumo Syringe with/without Needle, manufactured by Terumo (Philippines) Corporation – Primary Predicate

K123588 – Intradermal Adapter manufactured by West Pharmaceutical Services, Inc.

[2] Laurent A, et al. *Echographic measurement of skin thickness in adults by high frequency ultrasound to assess the appropriate microneedle length for intradermal delivery of vaccines.* Vaccine 2007; **25**(34):6423-6430.