December 21, 2021

Terumo Clinical Supply Co., Ltd.
c/o Vaibhav Sivaramakrishan, Terumo Medical Corporation
Regulatory Affairs Specialist II
265 Davidson Ave., Suite 320
Somerset, New Jersey 08873

Re: K211078
Trade/Device Name: Progreat Lambda
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, KRA
Dated: November 30, 2021
Received: December 1, 2021

Dear Vaibhav Sivaramakrishan:

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,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211078

Device Name
Progreat Lambda

Indications for Use *(Describe)*
Progreat Lambda is intended for the infusion of contrast media, or embolic materials for hemostasis, into the peripheral vasculature, excluding the blood vessels belonging to the central circulatory system. Progreat Lambda is also indicated for drug infusion in intra-arterial therapy in the peripheral vasculature. Progreat Lambda should not be used in cerebral or coronary vessels.

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

K211078

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

Prepared by: **Vaibhav Sivaramakrishan**
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Prepared for: ***Owner/Operator***
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Date prepared: December 21, 2021

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

Proprietary Name:	Progreat Lambda
Common Name:	Micro Catheter System
Classification Name:	Diagnostic Intravascular Catheter (DQO), Continuous flush catheter (KRA)
Classification Panel:	Cardiovascular
Regulation:	21 CFR 870.1200
Product Code:	DQO, KRA
Classification:	Class II

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

The legally marketed device to which substantial equivalence is claimed is:

Primary Predicate Device:

1. K033583: PROGREAT, manufactured by Ashitaka Factory of Terumo Corporation

Reference Devices:

1. K173548: Merit Pursue Microcatheter, Merit Medical Systems, Inc.
2. K201792: TRUSELECT Microcatheter, Boston Scientific Corp.

D. REASON FOR 510(k) SUBMISSION

This Traditional 510(k) is being submitted for Progreat Lambda for the purposes of establishing substantial equivalence to a legally marketed predicate device.

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

Principle of Operation Technology

Progreat Lambda submitted in this 510(k) and its predicate Progreat (K033583) are operated by a manual process.

Design/Construction

Progreat Lambda is a single use, ethylene oxide sterilized device that is intended for the infusion of contrast media, or embolic materials for hemostasis, into the peripheral vasculature, excluding the blood vessels belonging to the central circulatory system. Progreat Lambda is also indicated for drug infusion in intra-arterial therapy in the peripheral vasculature. Progreat Lambda should not be used in cerebral or coronary vessels.

The catheter consists of metal wire mesh reinforced multi-layer polymer tubing. The mesh is embedded in the catheter wall the entire length of the catheter with the exception of the distal tip section. This increases the flexibility, kink resistance, and pressure resistance of the catheter. The inner layer of the catheter is made of PTFE (polytetrafluoroethylene) to ensure smooth movement of devices such as the guide wire.

The outer surface of the catheter is coated with a hydrophilic polymer with the exception of the proximal end that is 60cm from the catheter hub. The coating becomes lubricious when wet with saline solution or blood.

The device is offered in effective lengths of 110, 130, 150, 165 and 175 cm. French size and shaft outer and inner diameter are given in Table 5.1.

Table 5.1: Catheter size

French Size	Shaft Outer Diameter (mm)		Shaft Inner Diameter (mm)	
	Distal part	Proximal part	Distal part	Proximal part
1.7 Fr.	0.57	0.94	0.43	0.58
1.9 Fr.	0.64	0.94	0.48	0.60

Materials

The materials for Progreat Lambda are provided in Table 5.2.

Table 5.2: List of Materials

No.	Name of Component			Raw material
1*	Catheter	Shaft	Outer layer	Polyester Elastomer
				Pigment
2			Reinforcement wire	Tungsten
3*			Inner layer	Polytetrafluoroethylene
4*		Distal tip section	Outer layer	Polyester Elastomer
				Pigment
5*			Inner layer	Polytetrafluoroethylene
6		Radiopaque marker		Pt-Ir alloy
7*	Hydrophilic polymer coating			Dimethyl acrylamide - glycidyl methacrylate copolymer
8	Quick-drying glue			Cyanoacrylate
9*	Catheter hub			Polyamide
				Silicone
10	Catheter strain relief tube			Polyester elastomer
				Pigment

*Blood contacting material.

Specifications

The specifications for Progreat Lambda are provided in Table 5.3.

Table 5.3: Progreat Lambda Specifications

French Size		1.7 Fr.	1.9 Fr.
Catheter I.D. (mm)	**Distal**	0.43	0.48
	Proximal	0.58	0.60
Catheter O.D. (mm)	**Distal**	0.57	0.64
	proximal	0.94	0.94
Effective length (cm)*		110, 130, 150, 165, 175	
Coating length(cm)		50, 70, 90, 105, 115	
Maximum guidewire outer diameter		0.016”	

*The length from the proximal catheter strain relief tube to the catheter distal tip.

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

Progreat Lambda is intended for the infusion of contrast media, or embolic materials for hemostasis, into the peripheral vasculature, excluding the blood vessels belonging to the central circulatory system. Progreat Lambda is also indicated for drug infusion in intra-arterial therapy in the peripheral vasculature. Progreat Lambda should not be used in cerebral or coronary vessels.

The indications for use are equivalent to the predicate (K033583).

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

Progreat Lambda, the subject of this Traditional 510(k), is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate, K033583 –Progreat, manufactured by Ashitaka Factory of Terumo Corporation.

In addition to the above-listed primary predicate, TERUMO CLINICAL SUPPLY CO., LTD. has identified the following reference devices. These are market leading devices with the same intended use and basic design as the subject device. Because these devices are frequently used in clinical practice, TERUMO CLINICAL SUPPLY CO., LTD. felt it was appropriate to use them as references when setting the acceptance criteria for Progreat Lambda performance testing.

1. Merit Medical Systems, Inc: Merit Pursue Microcatheter (K173548)
2. Boston Scientific Corp.: TRUSELECT Microcatheter (K201792)

A comparison of the technological characteristics is summarized in Table 5.4.

Table 5.4: Summary of Comparative Information

Device Characteristic	Subject Device: Progreat Lambda	Predicate Device: Progreat K033583	Reference Device #1: Merit Pursue Microcatheter K173548	Reference Device #2: TRUSELECT™ Microcatheter K201792
Manufacturer	TERUMO CLINICAL SUPPLY CO., LTD.	Ashitaka Factory of Terumo Corporation	Merit Medical Systems, Inc.	Boston Scientific Corporation
Intended Use /Indications for Use	Progreat Lambda is intended for the infusion of contrast media, or embolic materials for hemostasis, into the peripheral vasculature, excluding the blood vessels belonging to the central circulatory system. Progreat Lambda is also indicated for drug infusion in intra-arterial therapy in the peripheral vasculature. Progreat Lambda should not be used in cerebral or coronary vessels.	Progreat is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities, and all coronary vessels. Progreat is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis. Progreat should not be used in cerebral vessels.	The Microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, the Microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. The catheter should not be used in the cerebral vessels.	The TRUSELECT™ Microcatheters are intended for peripheral vascular use. The microcatheter can be used for selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.
Operation Principle	Manual	Same	Same	Same

Device Characteristic	Subject Device: Progreat Lambda	Predicate Device: Progreat K033583	Reference Device #1: Merit Pursue Microcatheter K173548	Reference Device #2: TRUSELECT™ Microcatheter K201792
Design/Construction	The catheter consists of inner layer, reinforcement wire, outer layer, radiopaque marker, hydrophilic polymer coating, catheter hub and catheter strain relief tube.	Same	Same	Same
Materials	Outer tube*: Polyester Elastomer Inner tube*: PTFE Reinforcement wire: Tungsten Radiopaque marker: Pt-Ir alloy Coating*: Dimethyl acrylamide glycidyl methacrylate copolymer, Silicone Catheter hub*: Polyamide, Silicone Catheter strain relief tube: Polyester elastomer *: blood contacting material	Outer layer*: Polyester elastomer (distal) and Polyurethane elastomer (proximal) Inner layer*: Polytetrafluoroethylene Reinforcing coil: Tungsten Radiopaque maker: Pt-Ir alloy Hydrophilic coating*: Dimethyl acrylamide – glycidyl methacrylate copolymer Hub*: Nylon Anti-kink protector: Nylon elastomer *: blood contacting material	Information not publicly available.	Information not publicly available.

Device Characteristic	Subject Device: Progreat Lambda	Predicate Device: Progreat K033583	Reference Device #1: Merit Pursue Microcatheter K173548	Reference Device #2: TRUSELECT™ Microcatheter K201792
Package	• Individual package on which the product label and the peel-off labels are attached • 1 unit per package	Same	Same	Same
Specifications	• Effective lengths: 110, 130, 150, 165, 175 cm • French size: 1.7Fr., 1.9Fr. • O.D.(Distal/Proximal) 1.7Fr./2.8Fr.:0.57/0.94mm 1.9Fr./2.8Fr.:0.64/0.94mm	• Effective lengths: 100, 110, 130, 150 cm • French size: 2.0, 2.4, 2.7, 2.8 Fr. • O.D.(Distal/Proximal) 2.0Fr./2.7Fr (0.67/0.90mm) 2.4/2.9Fr. (0.80/0.97mm) 2.7/2.9Fr. (0.90/0.97mm) 2.8/3.0Fr. (0.93/1.00mm)	• Effective Length: 110, 130, 150cm • French size: 1.7Fr., 2.0Fr. O.D.(Distal/Proximal) 1.7Fr./2.8Fr. 2.0Fr./2.9Fr.	• Effective Length: 105, 130, 150, 175cm • French size: 2.0Fr. O.D.(Distal/Proximal) 2.0Fr./2.8Fr.

Device Characteristic	Subject Device: Progreat Lambda	Predicate Device: PROGREAT K033583	Reference Device #1: Merit Pursue Microcatheter K173548	Reference Device #2: TRUSELECT™ Microcatheter K201792
Specifications	• I.D. 1.7Fr.: 0.43mm 1.9Fr.: 0.48mm • Maximum Guide Wire outer diameter: 0.016"	• I.D. 2.0Fr.:0.019"/0.49mm 2.4Fr.:0.022"/0.57mm 2.7Fr.:0.025"/0.65mm 2.8Fr.:0.027"/0.70mm • Maximum Guide Wire outer diameter: 2.0Fr.type: 0.016" 2.4Fr.type: 0.018" 2.7Fr.type: 0.021" 2.8Fr.type: 0.021"	• I.D. 1.7Fr.type: 0.016" (0.40 mm) 2.0Fr.type: 0.020" (0.50 mm) •Maximum guidewire outer diameter: 1.7Fr.type: 0.014" 2.0Fr.type: 0.018"	• I.D. 0.021”(0.53mm) •Maximum guidewire outer diameter: 0.016” or 0.014”
Specifications	• Distal tip shape: Straight/Angle/Triple angle • Maximum injection pressure: 900 psi	• Distal tip shape: straight/angled • Maximum injection pressure: 2.0Fr. : 750psi 2.4, 2.7Fr.: 750psi 2.8Fr. : 900 psi	• Distal tip shape: straight/angled • Maximum injection pressure: 800 psi	• Distal tip shape: straight/angled(Bern-shape) • Maximum injection pressure: 800 psi
Sterilization	Ethylene oxide	Same	Same	Same
Shelf life	2 years	2 years	Information not publicly available.	Information not publicly available.

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

Performance Testing

Performance testing was conducted to ensure the safety and effectiveness of Progreat Lambda throughout the shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device. With the exception of the Radio-detectability[1] test and Embolic device compatibility for coil and microsphere[2], the following performance tests were performed on non-aged and accelerated aged samples. Table 5.5 provides a list of performance tests that were performed on Progreat Lambda.

Table 5.5: Summary of Performance Testing

Test Item
Radio-detectability
Surface
Peak tensile force
Freedom from leakage
Fluid leakage (Hub)
Sub-atmospheric pressure air leakage (Hub)
Stress cracking (Hub)
Resistance to separation from axial load (Hub)
Resistance to separation from unscrewing (Hub)
Resistance to overriding (Hub)
Power injection
Distal tip
Particulate evaluation
Coating integrity
Torque strength
Distal marker strength
Product dimension
Embolic device compatibility
Flexibility and kink test
Wire compatibility
Simulated Use

[1] Only non-aged sample was tested since the amount of metallic material contained in the product would not change over time.
[2] Only non-aged sample was tested since the inner diameter would not changed over time.

Performance testing met the predetermined acceptance criteria and is acceptable for clinical use throughout its shelf life.

Biocompatibility

In accordance with ISO 10993-1, Progreat Lambda is classified as: Externally Communicating Device, Circulating Blood, Limited Contact (<24 hours). The finished device's patient contacting parts were tested in accordance with the 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 accelerated aged devices to show that the biocompatibility is maintained throughout the shelf life of the product. Table 5.6 provides a list of biocompatibility tests conducted on Progreat Lambda.

Table 5.6: Summary of ISO 10993 Biocompatibility Testing

Non-aged, sterile, whole device
Cytotoxicity
Sensitization
Intracutaneous Reactivity
Acute Systemic Toxicity
Pyrogenicity
Hemolysis
Thrombogenicity
Complement Activation (Immunology)
Physicochemical Profile (Physicochemical and FT-IR)
Accelerated-aged (3 years), sterile, whole device
Cytotoxicity
Hemolysis
Physicochemical Profile (Physicochemical and FT-IR)

Results of the testing demonstrate that the device is biocompatible throughout the shelf life of the product.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014, *Sterilization of Health Care Products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices,* to provide a Sterility Assurance Level (SAL) of 10^{-6}.

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

This 510(k) does not include data from clinical tests.

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

In summary, Progreat Lambda, subject of this 510(k), is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate, K033583–Progreat, manufactured by Ashitaka Factory of Terumo Corporation.