



July 21, 2017

Food and Drug Administration  
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Ashitaka Factory of Terumo Corporation  
% Lauren Nitahara  
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Re: K170223  
Trade/Device Name: Progreat  
Regulation Number: 21 CFR 870.1200  
Regulation Name: Diagnostic Intravascular Catheter  
Regulatory Class: Class II  
Product Code: DQO  
Dated: June 30, 2017  
Received: June 30, 2017

Dear Lauren Nitahara:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

  
Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K170223

Device Name

Progreat

Indications for Use (Describe)

The 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. The Progreat is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis. The Progreat should not be used in cerebral 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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**K170223**

**510(k) SUMMARY**

*A summary of 510(k) safety and effectiveness information in accordance  
with the requirements of 21 CFR 807.92.*

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

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Date Prepared: January 24, 2017

**B. DEVICE NAME (807.92(A)(2))**

*Proprietary Name:* Progreat  
*Common Name:* Continuous Flush Infusion Catheter  
*Classification Name:* Continuous flush catheter  
*Regulation Number:* 21 CFR 870.1210  
*Regulatory Class:* Class II  
*Review Panel:* Cardiovascular  
*Product Code:* DQO

**C. PREDICATE DEVICE (807.92(A)(3))**

The legally marketed device(s) to which substantial equivalence is claimed:

- K033583, Terumo Progreat, manufactured by Ashitaka Factory of Terumo Corporation

**D. REASON FOR 510(K) SUBMISSION**

This Traditional 510(k) is being submitted in order to add a 0.018” guidewire to the 2.4 Fr Progreat catheter (K033583) for the purposes of establishing substantial equivalence to a legally marketed device. The 2.4 Fr Progreat catheter and 0.018” guidewire will be marketed as a combined unit and will be an extension of the existing Progreat product family.

There is no change between the subject and predicate with respect to indications for use or technology as a result of this submission.

**E. DEVICE DESCRIPTION (807.92(A)(4))**

***Principle of Operation Technology***

The Progreat (2.4 Fr Catheter with 0.018” Guidewire) submitted in this 510(k) and its predicate Progreat (K033583) are operated by a manual process.

***Design / Construction***

The Progreat catheter consists of metal coil reinforced multi-layer polymer tubing with a hydrophilic coating. The guidewire is comprised of an alloy core wire with radiopaque marker and hydrophilic coating. The subject 2.4 Fr Progreat catheter and 0.018” guidewire will be marketed as a combined unit and will be an extension of the existing Progreat product family. The design and technological characteristics of the subject 2.4 Fr Progreat with 0.018” guidewire are identical to the predicate 2.7 Fr Progreat with 0.021” guidewire.

The Progreat catheter is available with or without accessories. The accessories to the catheter are supplied in different configurations depending on the product code:

- The Guidewire has a super-elastic alloy core and is surface coated with a hydrophilic polymer.
- The Inserter is used to assist the physician in the placement of the guidewire within the catheter.
- The Catheter Mandrel (stylet) is used in the shaping of the catheter for procedures that require a catheter with a tip configuration other than straight.
- The Syringe is used in the priming of the catheter.
- The Wire Stopper can be clipped onto the guide wire to adjust the length of the guidewire that extends past the catheter tip.
- The Catheter Stopper S can be clipped onto the catheter to adjust the insertion length of the catheter.
- The Y-connector can be used to connect a power injector unit to the end of the catheter for infusion of contrast media.

**Device Specifications**

The specifications for the Progreat are provided in the table below:

**Table 5.1:** Device Specifications

Name of Component		Modified Progreat	Current Progreat
<b>Catheter*</b>	<i>Catheter Size</i>	2.4 Fr	2.0, 2.4, 2.7, 2.8 Fr
	<i>Catheter OD (Distal End)</i>	0.77 ~ 0.84 mm	2.0 Fr.: 0.64 ~ 0.71 mm 2.4 Fr.: 0.77 ~ 0.84 mm 2.7 Fr.: 0.87 ~ 0.93 mm 2.8 Fr.: 0.90 ~ 0.96 mm
	<i>Catheter OD (Proximal End)</i>	0.88 ~ 0.99 mm	2.0 Fr.: 0.84 ~ 0.94 mm 2.4 Fr.: 0.88 ~ 0.99 mm 2.7 Fr.: 0.91 ~ 0.99 mm 2.8 Fr.: 0.94 ~ 1.00 mm
	<i>Catheter Effective Lengths<sup>†</sup></i>	100, 110, 130, 150 cm	100 ~ 150 cm
	<i>Part without Hydrophilic Coating (from the proximal end)</i>	60 cm	60 cm
<b>Guidewire</b>	<i>Wire Diameter</i>	0.018”	0.021”
	<i>Wire Distal Tip Shape</i>	Angled (70 degree) and Double Angled	Angled (70 degree)
	<i>Wire Protruding Length<sup>‡</sup></i>	100 mm	5 ~ 300 mm
<b>Accessories</b>		Inserter Catheter Mandrel (stylet) 2.5 ml Syringe with Lock Wire Stopper Catheter Stopper S Y-connector	Inserter Catheter Mandrel (stylet) 2.5 ml Syringe with Lock Wire Stopper Catheter Stopper S Y-connector

\* Catheter is 510(k) cleared under K033583.

† The length from the proximal anti-kink protector to the catheter distal tip.

‡ Guide wire protruding length is the length that the guide wire extends past the catheter tip.

Note: For the purposes of this submission, the Progreat under review is referred to as “Progreat (2.4 Fr Catheter with 0.018” Guidewire).” This Progreat (2.4 Fr Catheter with 0.018” Guidewire) will be added to the current products, which include the above specifications as cleared under K033583.



**F. INDICATIONS FOR USE (807.92(A)(5))**

The 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. The Progreat is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis. The Progreat should not be used in cerebral vessels.

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

**G. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(A)(6))**

The Progreat (2.4 Fr. Catheter with 0.018” Guidewire) is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to:

- K033583, Terumo Progreat, manufactured by Ashitaka Factory of Terumo Corporation

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

**Table 5.2:** Summary of Comparative Information

<b>Characteristic</b>	<b>Modified Progreat</b>	<b>Current Progreat</b>
<b><i>Manufacturer</i></b>	Ashitaka Factory of Terumo Corporation	Identical
<b><i>Intended Use / Indication for Use</i></b>	The 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. The Progreat is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis. The Progreat should not be used in cerebral vessels.	Identical
<b><i>Operation Principle</i></b>	Manual	Identical
<b><i>Design/ Construction</i></b>	The catheter consists of metal coil reinforced multi-layer polymer tubing with hydrophilic coating. The guidewire has a super-elastic alloy core with a hydrophilic coating and 0.018” diameter. Accessories consist of Inserter, Catheter Mandrel (stylet), Syringe, Wire Stopper, Catheter Stopper S, Y-connector.	Identical material and construction Guidewire diameter: 0.021”
<b><i>Package</i></b>	Individual package on which the product label and the peel-off labels are attached. The device is provided as 1 unit per package	Identical
<b><i>Specifications</i></b>	Effective length: 100, 110, 130, 150 cm Catheter size: 2.4 Fr. Guidewire size: 0.018”	Effective length: 100-150 cm Catheter size: 2.0, 2.4, 2.7, 2.8 Fr. Guidewire size: 0.021”
<b><i>Sterilization</i></b>	Ethylene oxide	Identical
<b><i>Shelf life</i></b>	2 years	Identical

## H. NON-CLINICAL TESTS (807.92(B)(1))

### *Performance Testing*

Performance testing was conducted to ensure the safety and effectiveness of the Progreat throughout the shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device. The majority of the following performance tests were performed on non-aged and accelerated aged samples; Radio-detectability testing was performed on a non-aged sample since the metallic material which generates radiopacity does not change over time. The following performance tests were performed on the Progreat device:

- Surface
- Radio-detectability
- Fracture test
- Flexing test
- Peak tensile force of guidewire
- Torque Strength
- Torqueability
- Tip Flexibility
- Sliding resistance
- Particulate evaluation
- Bending strength
- Hermeticity test
- Shaping test
- Product dimensions

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

***Biocompatibility***

All the materials used in the subject Progreat (2.4 Fr Catheter with 0.018” Guidewire) are identical to the predicate Progreat (K033583). Both the subject Progreat and the predicate Progreat are identical in intended use, materials formulation, processing, sterilization, and geometry (with the addition of the length and guidewire diameter). Therefore, the differences between the subject Progreat and predicate Progreat do not raise any new concerns regarding the biocompatibility of the device.

***Sterilization***

The sterilization method used in the subject Progreat (2.4 Fr Catheter with 0.018” Guidewire) is identical to the predicate Progreat (K033583). Therefore, differences between the subject Progreat and predicate Progreat do not raise any new concerns regarding the sterilization of the device.

**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, the Progreat (2.4 Fr Catheter with 0.018” Guidewire), subject of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate Progreat (K033583), manufactured by Ashitaka Factory of Terumo Corporation.