DEC 1 2 2003

SECTION II. SUMMARY AND CERTIFICATION

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

A. Device Name

Proprietary Name	PROGREAT
Classification Name	Diagnostic Intravascular Catheter
Common Name	Angiographic Catheter

B. Intended Use

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

Note: This is the same intended use as the predicate device – GT LEGGIERO K981359.

C. Device Description

The PROGREAT catheter is available with or without the following accessories: guide wire, inserter, mandrel (stylet), syringe, wire stopper, and Y-connector.

The catheter consists of metal coil reinforced multi-layer polymer tubing. The coil is embedded in the catheter wall the entire length of the catheter. 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 which becomes lubricious when wet with saline solution or blood.

The following are accessories to the catheter and will be supplied in different configurations depending on the product code:

The guide wire has a super-elastic alloy core and is surface coated with a hydrophilic polymer. This enhances advancement of the guide wire into a peripheral vessel.

The inserter is used to assist the physician in the placement of the guide wire within the catheter.

The 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 syringe can be filled with heparinized saline solution and then this solution can be injected into the catheter.

The wire stopper can be clipped onto the guide wire to adjust the protruding length of the guide wire.

The Y-connector can be used to connect a power injector unit to the end of the catheter for infusion of contrast media.

D. Principle of Operation / Technology

The PROGREAT catheter and the accessories included in this 510(k) are operated manually or by a manual process.

E. Design / Materials

Differences in materials between the PROGREAT catheter and the GT LEGGIERO K981359 raise no new issues of safety and effectiveness.

F. *Specifications*

Part	Progreat Catheter	GT LEGGIERO K981359
Available Sizes (Fr.)	2.8/2.7/2.4/2.0	2.9
Catheter length	100-150	100-150
Guide wire size	0.021"	none
Accessories	**With guide wire-** Syringe, inserter, Y-connector, mandrel (stylet), and wire stopper **Without guide wire-** Mandrel (stylet)	Y-connector, mandrel (stylet)

Note: The syringe (2.5ml) is cleared under 510(k) K771205. The guide wire, inserter, Y-connector, and mandrel (stylet) are the same devices cleared under 510(k) K915414, Terumo Angiographic Catheter and K981359, GT Leggiero Catheter.

G. *Performance*

The PROGREAT catheter is available with or without the following accessories: guide wire, inserter, mandrel (stylet), syringe, wire stopper, and Y-connector. The wire stopper is a new accessory, all of the additional accessories are the same as the ones used with currently approved devices.

The following verification tests were performed to demonstrate the substantial equivalence of the modified device (PROGREAT catheter) to the unmodified device (GT LEGGIERO K981359).

- Ease of removal from holder
- Frictional resistance of catheter and guide wire
- Joint strength of hub on catheter and guide wire
- Pressure resistance of catheter
- Kink resistance

None of the data raises any new issues of safety and effectiveness. Additionally, a risk analysis was conducted and there were no new issues of safety and effectiveness.

Therefore the performance of the Progreat Catheter is substantially equivalent to the performance of the GT LEGGIERO, cleared under K981359.

H. Additional Safety Information

Manufacturing controls include visual, functional, dimensional and sterility tests.

The PROGREAT catheter is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤24 hrs). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible.

Sterilization conditions have been validated in accordance to AAMI/ANSI/ISO 11135 Medical Devices-Validation and Routine Control of Ethylene Oxide Sterilization. The device is sterilized to a SAL of 10^{-6}. ETO residuals for the PROGREAT will not exceed the maximum limits proposed for Part 821 of Title 21 in FR June 23, 1978 (or as finalized or amended).

I. Substantial Equivalence

The PROGREAT catheter is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the Terumo GT LEGGIERO, cleared under K981359. Differences between the two devices do not raise any significant issues of safety or effectiveness.

J. Submitter Information

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Date Prepared: November 11, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2003

Terumo Medical Corporation
c/o Mr. Mark Unterreiner
Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, MD 21921

Re: K033583
PROGREAT
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: November 11, 2003
Received: November 13, 2003

Dear Mr. Unterreiner:

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.

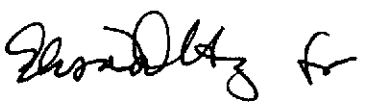
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Note: This is the same intended use as the predicate device, K981359

510(k) Number (if known): K033583

Device Name: PROGREAT

Indications For Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

12/11/03

(Division Sign-off)
Division of Cardiovascular Devices

510(K) Number K033583 (SM. K)