

JAN 27 1999

SECTION II Summary and Certification

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
PERTAINING TO
SUBSTANTIAL EQUIVALENCE**

Proprietary Device Name: GT LEGGIERO

Classification Name: Catheter, Angiographic

INTENDED USE

The GT Leggiero 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 GT Leggiero 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 Terumo Angiographic Catheter (SP Catheter) cleared under 510(k) K915414.

DESCRIPTION

The GT Leggiero™ Catheter is a multilayer single-lumen catheter 100-150cm in length with a maximum injection pressure of 450 psi. The catheter shaft is reinforced the entire length by helically-cut stainless steel piping. The distal 15cm is fine-worked for high flexibility. The catheter is 2.9Fr. size (~0.96mm in outer diameter) and can be used with a guiding catheter 0.047" (1.20mm) or larger inner diameter. The catheter shaft has an inner diameter of ~0.6mm to admit a 0.018" or smaller sized guide wire. The catheter has a hydrophilic polymer coating on the outer surface with the exception of 30cm from its proximal end. A radiopaque marker (~0.8mm) is incorporated in the catheter tip for increased radiopacity.

Note:

The catheter will be supplied with a Y-Connector and Stainless Steel shaping Mandrel.

SECTION II Summary and Certification

SUBSTANTIAL EQUIVALENCE

The GT Leggiero™ Catheter submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo Angiographic Catheter (SP Catheter) K915414.

PRINCIPLE OF OPERATION/TECHNOLOGY

The GT Leggiero and Terumo Angiographic Catheter (SP Catheter) are operated manually or by a manual process.

DESIGN/MATERIALS

Differences in materials between the GT Leggiero and the Terumo Angiographic Catheter (SP Catheter) raise no new issues of safety and effectiveness.

SPECIFICATIONS

<u>Parts</u>	<u>GT Leggiero</u>	<u>Cleared Terumo Angiographic Catheter (SP Catheter) K915414</u>
Outer diameter	2.9Fr. (0.96mm)	3.0Fr. (1.00mm)
Inner diameter	0.60mm	0.70mm
Catheter Length	100-150cm	100cm & 130cm

SECTION II Summary and Certification

PERFORMANCE

The performance of the GT Leggiero is substantially equivalent to the performance of the cleared Terumo Angiographic Catheter (SP Catheter) K915414.

The following tests were performed demonstrating the substantial equivalence of the GT Leggiero submitted in this 510(k) to the cleared Terumo Angiographic Catheter (SP Catheter) K915414.

- Flexibility Test
- Tensile Strength
- Maximum Pressure Test
- Flow Rate Test

ADDITIONAL SAFETY INFORMATION

Sterilization conditions have been validated according to the AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10 to the negative sixth.

Ethylene oxide residuals will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal register of June 23, 1978 (or as finalized or amended).

Manufacturing control test methods include: functional, extraction and sterility tests.

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." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) contact duration]. The blood contacting materials were found to be biocompatible.

The expiration dating for the GT Leggiero will be 24 months.

SECTION II Summary and Certification

CONCLUSION

The Terumo GT Leggiero submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo Angiographic Catheter (SP Catheter) K915414. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Date Prepared	April 9, 1998
Prepared by	Keith M. Smith Senior Regulatory Affairs Associate Regulatory Affairs
Prepared for	Terumo Medical Corporation 125 Blue Ball Road Elkton, MD 21921 Phone (410) 392-7375 or (410) 392-7231 Fax (410) 398-6079



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 1999

Ms. Yuk-Ting Lewis
Senior Regulatory Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K981359
Trade Name: GT Leggiero Catheter
Regulatory Class: II
Product Code: DQY
Dated: October 23, 1998
Received: October 29, 1998

Dear Ms. Lewis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

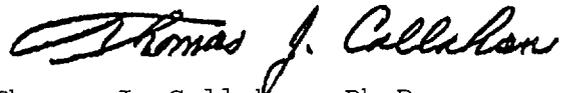
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation

you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981359

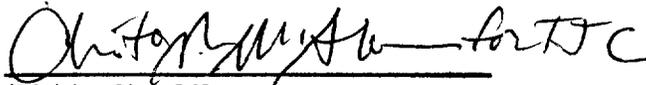
Device Name: GT Leggiero Catheter

Indications For Use:

The GT Leggiero 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 GT Leggiero 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)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K981359

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use