

II. SUMMARY AND CERTIFICATION

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

A. *Device Name*

Proprietary Name: RADIFOCUS® Optitorque

Classification Name: Angiographic Catheter

Common Name: Angiographic Catheter

B. *Intended Use*

The RADIFOCUS® Optitorque Angiographic Catheter is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system.

Note: This is the same intended use as the RADIFOCUS® Angiographic Catheter, K863137/A.

C. *Device Description*

The RADIFOCUS® Optitorque Angiographic Catheter is a two-layer construction comprised of a stainless steel mesh sandwiched between layers of polyurethane polyamide elastomer. The polyurethane polyamide elastomer contains barium sulfate for visibility and contrast under fluoroscopy. The Catheter has a "soft-tip" whose purpose is to minimize trauma to the vessel wall. The soft-tip is a flexible, supple polyurethane tip that is permanently welded to the catheter shaft. The soft tip is approximately 0.5~1.5 mm long on the 4Fr. Optitorque Catheter. It is approximately 1.0~2.5mm long on the 5 and 6Fr. Optitorque Catheters.

D. *Substantial Equivalence*

The RADIFOCUS® Optitorque Angiographic Catheter submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the cleared RADIFOCUS® Angiographic Catheter, (K863137/A), the Terumo Angiographic Catheter (K915414) and the Cordis Infiniti Angiographic Catheter (K960975).

E. *Principle Of Operation / Technology*

The RADIFOCUS® Optitorque Angiographic Catheter is operated manually or by a manual process.

F. *Design / Materials*

Differences in materials between the RADIFOCUS® Optitorque Angiographic Catheter and the RADIFOCUS® Angiographic Catheter, K863137/A, raise no new issues of safety and effectiveness.

G. Specifications

	Optitorque Angiographic Catheter	Angiographic Catheter, K863137/A
Available Sizes	4 – 6 Fr.	5 – 8 Fr.
Catheter Length	650 – 1200 mm	500 – 1300 mm
Maximum Injection Pressure	4 Fr.: 750 psi 5, 6 Fr.: 1000 psi --- ---	--- 5, 6 Fr.: 1000 psi 7 Fr.: 800 psi 8 Fr.: 700 psi

H. Performance

The following verification tests were performed to demonstrate the substantial equivalence of the Optitorque Angiographic Catheter to the Angiographic Catheter, K863137/A.

- Tensile strength on the shaft, hub and soft tip
- Rigidity
- Maximum Pressure Test
- Torque Transmission Test
- Flow Rate Test
- Tip Flexibility Test
- Delivery of Therapeutic Agents
- Biocompatibility Tests

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 Optitorque Angiographic Catheter is substantially equivalent to the performance of the Angiographic Catheter, cleared under K863137/A.

I. Additional Safety Information

Manufacturing controls include visual, functional (which including dimensional), chemical, biological and sterility tests.

The Optitorque Angiographic 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.

J. Conclusion

The RADIFOCUS® Optitorque Angiographic Catheter is substantially equivalent in intended use, design, technology / principles of operation, materials and performance to the RADIFOCUS® Angiographic Catheter (K863137/A), the Terumo Angiographic Catheter (K915414) and the Cordis Infiniti Angiographic Catheter (K960975). Differences between the devices do not raise any significant issues of safety or effectiveness.

Date Prepared: June 17, 1999

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 10 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K992051
Trade Name: RADIFOCUS® Optitorque™ Angiographic Catheter
Regulatory Class: II
Product Code: DQO
Dated: July 12, 1999
Received: July 13, 1999

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 (Pre-market 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 pre-market 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

Note: This is the same intended use as the unmodified device, K863137/A

510(k) Number (if known): _____

Device Name: RADIFOCUS® Optitorque™ Angiographic Catheter

Indications For Use:

The RADIFOCUS® Optitorque Angiographic Catheter is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system.

Christopher M. [Signature] for Callahan

(Division Sign Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992051

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)