DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 19, 2015

Ashitaka Factory of Terumo Corporation
Monika McDole-Russell
Senior Regulatory Affairs Specialist
Terumo Medical Corporation
265 Davidson Ave., Suite 320
Somerset, New Jersey 08873

Re: K150232
Trade/Device Name: Radifocus® Optitorque™ Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: September 17, 2015
Received: September 18, 2015

Dear Monika McDole-Russell:

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 yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K150232

Device Name
Radifocus Optitorque Angiographic Catheter

Indications for Use *(Describe)*
The Radifocus Optitorque Angiographic Catheter is indicated for use in cardiac and vascular procedures. It is designed to deliver radiopaque media, guide wires, catheters, and therapeutic agents to selected sites in the vascular system. The different shapes are designed to selectively engage arteries from access sites such as the femoral, radial, and brachial artery.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K150232 – 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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510(k) SUMMARY

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

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Date prepared: October 19, 2015

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

Proprietary Name:	Radifocus Optitorque Angiographic Catheter
Common Name:	Angiographic, Catheter
Classification Name:	Diagnostic Intravascular Catheter
Classification Panel:	Cardiovascular
Regulation:	21 CFR 870.1200
Product Code:	DQO
Classification:	Class II

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

The legally marketed device(s) to which substantial equivalence is claimed is K082736 Radifocus Optitorque Angiographic Catheter, manufactured by Ashitaka Factory of Terumo Corporation in Japan.

D. REASON FOR 510(K) SUBMISSION

This premarket notification is being submitted due to a raw material change in the catheter shaft (outer layer) of the device. The current polyamide elastomer material is no longer available from the vendor and has been replaced with an equivalent polyamide elastomer. Biocompatibility testing has been completed to demonstrate that the raw material change has not affected the safety and performance of the device. The IFU is also being revised to update the flow rate table and add a contraindication; the addition of the contraindication is to bring the IFU into alignment with wording recommended in FDA draft guidance *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (issued April 23, 2013)*. Additionally, a clarification is being made to the wording of the Indications for Use; however, no changes are being made to the actual indications previously cleared under K082736.

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

The Radifocus Optitorque Angiographic Catheter is comprised of a two-layer construction featuring stainless steel mesh sandwiched between layers of polyurethane and polyamide elastomers. The shaft inner layer and outer layer contain barium sulfate for visibility and contrast under fluoroscopy. A soft tip is attached to the distal portion of some 4 Fr and all 5 Fr and 6 Fr catheters except those with a pigtail design; a soft tube is attached to the distal portion of 5 Fr and 6 Fr catheters with a pigtail design; the 4 Fr products are available with or without a soft tip. Constructed of flexible, supple polyurethane that is permanently welded to the catheter shaft, the soft tip and soft tube are designed to minimize trauma to the vessel wall. There is no change to the design of the device as a result of this submission.

The device is offered in lengths of 65-120 cm. French sizes and shaft inner diameters are as follows:

French Size	Shaft Inner Diameter
4	1.05mm
5	1.22mm
6	1.32mm

It is a disposable device intended for single use only. This device is individually packaged and sterilized by ethylene oxide gas.

F. INTENDED USE (807.92(a)(5))

The Radifocus Optitorque Angiographic Catheter is intended for use in cardiac and vascular procedures. It is designed to deliver radiopaque media, guide wires, catheters, and therapeutic agents to selected sites in the vascular system. The different shapes are designed to selectively engage arteries from access sites such as the femoral, radial, and brachial artery.

Note: This intended use is identical to the predicate device, Radifocus Optitorque Angiographic Catheter (K082736).

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

The Radifocus Optitorque Angiographic Catheter with the new material, the subject of this Traditional 510(k), is substantially equivalent in its intended use/indications for use, technology/principal of operation, materials, and performance to the currently marketed Radifocus Optitorque Angiographic Catheter, manufactured by Ashitaka Factory of Terumo Corporation and cleared under K082736.

A comparison of the intended use/indications for use and technological characteristics are summarized in the table below. The raw material change and addition of a contraindication to the IFU do not negatively impact the safety and effectiveness of the device.

Note: A statement of substantial equivalence to another product is required by 21CFR807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is, therefore, not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "…a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977)

Table 5.1: Device Comparison Table

<table>
<tr><th colspan="2">Device Characteristic</th><th>Predicate Device: Radifocus Optitorque Angiographic Catheter (K082736)</th><th>Subject Device: Radifocus Optitorque Angiographic Catheter</th></tr>
<tr><td colspan="2">Manufacturer</td><td>Ashitaka Factory of Terumo Corporation</td><td>Same</td></tr>
<tr><td rowspan="3">Intended Use/Indications for Use</td><td>Indications for Use</td><td>The Radifocus Optitorque Angiographic Catheter is intended for cardiac and vascular procedures. It is designed to deliver radiopaque media, guide wires, catheters, and therapeutic agents to selected sites in the vascular system. The different shapes are designed to selectively engage arteries from access sites such as the femoral, radial, and brachial artery.</td><td>The Radifocus Optitorque Angiographic Catheter is indicated for use in cardiac and vascular procedures. It is designed to deliver radiopaque media, guide wires, catheters, and therapeutic agents to selected sites in the vascular system. The different shapes are designed to selectively engage arteries from access sites such as the femoral, radial, and brachial artery.</td></tr>
<tr><td>Contraindic-ations</td><td>Contraindications cleared under K082736</td><td>Contraindications cleared under K082736, plus the following statement: “Patients with a contraindication to anti-platelet and/or anti-coagulation therapy”</td></tr>
<tr><td>Warnings and Precautions</td><td>Warnings and precautions cleared under K082736</td><td>Warnings and precautions cleared under K082736, plus the maximum flow rate of saline was added in accordance with 6.3. (i) of ISO 10555-1:2013.</td></tr>
<tr><td colspan="2">Operation Principle</td><td>Manual</td><td>Same</td></tr>
<tr><td colspan="2">Design / Construction</td><td>Catheter assembly (shaft, hub, soft tip/soft tube, strain relief/inserter, hub support tube (4 Fr only))

<table>
<tr><th>Fr</th><th>Distal Part</th><th>Proximal Part</th></tr>
<tr><td rowspan="2">4</td><td>Soft tip</td><td>Strain Relief</td></tr>
<tr><td>-</td><td>Inserter</td></tr>
<tr><td rowspan="2">5, 6</td><td>Soft tip</td><td>Strain Relief</td></tr>
<tr><td>Soft tube</td><td>Inserter</td></tr>
</table></td><td>Same</td></tr>
<tr><td colspan="2">Materials</td><td>• Shaft
o Inner Layer – Polyamide elastomer, Polyurethane elastomer
o Braid – Stainless steel
o Outer Layer – Polyamide elastomer, Polyurethane elastomer</td><td>• Shaft
o Inner Layer – Same
o Braid – Same
o Outer Layer – Polyamide elastomer, Polyurethane elastomer</td></tr>
</table>

Device Characteristic		**Predicate Device:** Radifocus Optitorque Angiographic Catheter (K082736)	**Subject Device:** Radifocus Optitorque Angiographic Catheter
		• Soft tip – Polyurethane elastomer • Soft tube (5 and 6 Fr only) – Polyurethane elastomer • Strain relief – Polyamide elastomer • Hub – Polyamide • Hub support tube (4 Fr only) – Polyurethane elastomer • Inserter – Polyethylene • Adhesive – Cyanoacrylate	• Soft tip – Same • Soft tube (5 and 6 Fr only) – Same • Strain relief – Same • Hub – Same • Hub support tube (4 Fr only) – Same • Inserter – Same • Adhesive – Same
Package		• Paperboard mount • individual package • Unit box • Shipping carton • Pouch	Same
Specifications	***Sizes/Shaft Inner Diameter***	4 Fr / 1.05mm 5 Fr / 1.22mm 6 Fr / 1.32mm	Same
	Lengths	65-120 cm	Same
	Maximum Labeled Injection Pressure	4 Fr: 750 psi 5 Fr and 6 Fr: 1000 psi	Same
Sterilization		Ethylene oxide	Same

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

Performance

Performance testing was conducted to ensure the safety and effectiveness of the Radifocus Optitorque Angiographic Catheter with the new raw material throughout the device's shelf life, verify conformity to the applicable parts of ISO standards, and demonstrate substantial equivalence to the predicate device.

No new issues of safety and effectiveness were raised with the testing performed.

The following tests were performed on non-aged and accelerated aged (3 yr.) samples according to currently accepted ISO standards:

Table 5.2: Performance Testing per ISO Standards

Test	Standard
Radio-detectability	ISO 10555-1:2013 Section 4.2 ASTM F640-12
Surface	ISO 10555-1:2013 Section 4.4
Peak tensile force	ISO 10555-1:2013 Section 4.6
Freedom from leakage	ISO 10555-1:2013 Section 4.7
Power injection	ISO 10555-1:2013 Section 4.10 Annex F and Annex G
Distal tip	ISO 10555-1:2013 Section 4.12
Flow rate	ISO 10555-1:2013 Section 6.3
Burst pressure	

All samples tested met the standard applicable to each test.

Additionally, performance testing other than to the above ISO Standards was performed on the device in accordance with Terumo's internal standards. The device complies with the acceptance criteria established for each test based on the predicate:

Table 5.3: Performance Testing per Internal Standards

Performance Test	Results
Shaft stiffness (Stiffness of braided-area)	Meets acceptance criteria
Torque transmission	Meets acceptance criteria
Torque strength	Meets acceptance criteria
Tensile strength (Shaft)	Meets acceptance criteria

Performance Test	Results
Bending strength	Meets acceptance criteria
Cleanliness	Meets acceptance criteria
Strength of hub junction	Meets acceptance criteria
Tensile Strength of soft tip	Meets acceptance criteria
Product dimensions (I.D.; O.D.; Tip I.D.; Tip O.D.; Length)	Meets acceptance criteria
Embolic cube testing	Meets acceptance criteria

Performance testing demonstrates that the Radifocus Optitorque Angiographic Catheter with the new raw material conforms to the recognized consensus ISO standards, is substantially equivalent to the predicate device, and is acceptable for clinical use throughout its shelf life.

Biocompatibility

The Radifocus Optitorque Angiographic Catheter with the new raw material is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (<24 hours). This is the same classification as the predicate Radifocus Optitorque Angiographic Catheter (K082736).

The finished device's blood/body contacting parts 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" and *Draft Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."* Tests were also performed on accelerated aged devices to ensure that biocompatibility is maintained throughout the shelf life of the product; results of the testing demonstrate that the device remains biocompatible throughout its shelf life.

Table 5.4: Biocompatibility Testing

Testing performed on non-aged, sterile, whole devices
Cytotoxicity
Sensitization
Intracutaneous Reactivity
Systemic Toxicity (acute)
Pyrogenicity
Hemolysis
Thrombogenicity
Complement Activation (Immunology)
Chemical Extraction
Testing performed on accelerated-aged (3 years), sterile, whole devices
Cytotoxicity
Hemolysis
Chemical Extraction

Pyrogen Testing

The Radifocus Optitorque Angiographic Catheter with the new raw material is certified to be non-pyrogenic in the unopened and undamaged package.
Pyrogen testing was performed in accordance with applicable ISO standards 10993-11 (2006) and ISO 10993-12 (2012) as well as United States Pharmacopeia 35, National Formulary 30, 2012 <151 > Pyrogen Test (USP Rabbit Test).

Sterilization

The sterilization conditions have been validated according to ISO 11135: 2014, Sterilization of Health Care Products - Ethylene Oxide - Requirements for development, validation and routine control of a sterilization process for medical devices, to provide a Sterility Assurance Level (SAL) of 10^{-6}. No changes have been made to the sterilization process for this device as a result of this submission.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) will meet requirements for limited exposure devices (contact up to 24 hours) prior to use based on ISO 10993-7, Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization residuals. Residual EO will not exceed 4 mg per device and residual ECH will not exceed 9 mg per device.

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971, taking into account the modifications to the previous device, and it was determined that any new risks were adequately captured and mitigated.

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

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

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

The Radifocus Optitorque Angiographic catheter with the new materials is substantially equivalent in intended use, principles of operation, design features, materials, performance and fundamental scientific technology when compared to the predicate Radifocus Optitorque (K082736). Verification testing was conducted and demonstrated that the modified device meets the design inputs and meets the same or equivalent requirements as the predicate Radifocus Optitorque for both ISO 10555-1 and internal standards. The differences between the predicate and proposed devices do not raise any new issues regarding safety and effectiveness. Therefore, the Radifocus Optitorque Angiographic catheter with the new materials is considered substantially equivalent to the predicate device.