K113335
Page 1 of 7

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JUL 16 2012

510(K) SUMMARY - HEARTRAIL™ III GUIDING CATHETER (5FR.)

1) Submitter Information

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Submitter's Name: Mr. Mark Unterreiner
Sr. Regulatory Affairs Specialist

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Date Prepared: January 30, 2012

2) *Device Name*

Proprietary Name:	Heartrail™ III Guiding Catheter
Common Name:	Guiding Catheter
Classification Name:	Catheter, Intravascular, Diagnostic

3) *Predicate Device*

The predicate device is the Terumo Heartrail™ III Guiding Catheter cleared under K092372. The differences between the devices do not raise any new issues of safety or effectiveness.

4) *Description*

The Heartrail™ III Guiding Catheter (5Fr.) is a three-layer construction comprised of a stainless steel mesh sandwiched between a layer of polytetrafluoroethylene and a layer of polyester elastomer. The polyester elastomer contains tungsten for visibility and contrast under fluoroscopy in the distal portion of the catheter. The Catheter has a "soft-tip" whose purpose is to minimize trauma to the vessel wall. The soft-tip is a flexible, supple polyester elastomer containing tungsten. This tip is permanently welded to the catheter shaft. Depending on the product code, the tip is either straight or curved into a specific shape.

The Heartrail™ III Guiding Catheter (5Fr.) is operated manually or by a manual process. During an interventional or diagnostic procedure, the physician will follow the standard procedure of placing a guide wire and introducer within a vessel. Then the Heartrail™ III Guiding Catheter would be advanced over the guide wire. Next, the guide wire and Guiding Catheter would be advanced to the target vessel. The Heartrail™ III Guiding Catheter can then be used for injection of radiopaque media or for support and exchange of guide wires, catheters, and/or therapeutic agents.

5) *Intended Use*

The Heartrail™ III Guiding 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 radial artery.

This is the same intended use as the unmodified device the Heartrail™ III Guiding Catheter cleared under K092372.

6) *Design / Materials/ Specifications*

The Heartrail™ III Guiding Catheter (5Fr.) in this submission uses similar materials as the Heartrail™ III Guiding Catheter cleared under K092372. Differences in materials between the devices do not raise any new issues of safety and effectiveness.

Part	Raw material
Soft tip*	Polyester elastomer containing tungsten
Inner layer*	Polytetrafluoroethylene
Braid	Stainless steel
Outer layer*	Polyester elastomer containing tungsten**
Strain relief	Polyester elastomer
Hub*	Nylon 12

* Blood contacting material
** Some parts of outer layer may not contain tungsten.

	Summary of Comparative Information Between the Modified Device and the Predicate Device	
	Before Device Modification Cleared Under K092372	**After Device Modification**
Trade name	Heartrail™ III Guiding Catheter (6Fr.)	Heartrail™ III Guiding Catheter (5Fr.)
Tip Shape/Material	AMPLATZ LEFT/ SHORT AMPLATZ/ AMPLATZ RIGHT/ BYPASS/ - - IKARI LEFT/ IKARI RIGHT/ TIGER-MODIFIED/ - - INTERNAL MAMMARY/ JUDKINS LEFT/ JUDKINS RIGHT/ MULTIPURPOSE Polyester elastomer containing tungsten	AMPLATZ LEFT/ SHORT AMPLATZ/ AMPLATZ RIGHT/ BYPASS/ BACKUP LEFT/ BACKUP LEFT-MODIFIED/ IKARI LEFT/ IKARI RIGHT/ TIGER-MODIFIED/ IKARI FEMORAL LEFT/ IKARI FEMORAL RIGHT/ INTERNAL MAMMARY/ JUDKINS LEFT/ JUDKINS RIGHT/ MULTIPURPOSE Polyester elastomer containing tungsten
Catheter O.D.	6Fr.	5Fr.
Usable length	100 cm	100 cm, 110cm
Maximum Injection Pressure	700 psi	700 psi

7) *Nonclinical Performance Testing*

The performance of the Heartrail™ III Guiding Catheter (5Fr.) is substantially equivalent to the performance of the predicate device. The equivalence was shown through bench testing. The following testing was performed on non-aged and aged devices:

1. Surface
2. Tip configuration
3. Product dimensions(O.D. ,effective length)
4. Force at break(1.shaft 2.hub)
5. Freedom from leakage
6. Radio detectability
7. Catheter burst /Leakage pressure
8. Flexibility / Catheter stiffness (1.shaft 2.distal)
9. Tip durability
10. Flow rate
11. Tip strength
12. Catheter inner surface friction
13. Torque control
14. Simulated use testing
15. Torque Strength
16. Flexibility and Kink Test
17. Catheter Bond Strength (1.soft tip 2:shaft)

8) Additional Safety Information

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 10993-1, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing within a risk management process.".

The catheter is classified as Externally Communicating Devices, Circulating Blood, limited Contact (<24 hrs). Results of the testing demonstrate that the blood contacting materials are biocompatible. The Heartrail™ III Guiding Catheter successfully passed all of the following biocompatibility tests:

Biocompatibility Testing on the Heartrail III Guiding Catheter (non-aged, sterile)		
Test	**Test Method**	**Result**
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Sensitization – NaCl and CSO Extract	ISO 10993-10	No evidence of causing delayed dermal contact sensitization.
Acute Intracutaneous Reactivity – NaCl and CSO Extract	ISO 10993- 10	No evidence of significant irritation or toxicity.
Acute Systemic Toxicity – NaCl and CSO Extract	ISO 10993-11	No mortality or evidence of systemic toxicity.
Hemolysis	ASTM F756	Non-hemolytic.
Pyrogen Study	ISO 10993-11	Non-pyrogenic.
InVivo Thromboresistance	ISO10993-4	Thromboresistant
Complement Activation Testing C3a	ISO10993-4	Not a complement system activator
Complement Activation Testing Sc5b-9	ISO10993-4	Not a complement system activator

Limited screening tests were conducted on the accelerated-aged[1], sterile device to demonstrate that aging does not affect the device's biocompatibility. The results are summarized in the table below.

Biocompatibility Testing on the Heartrail III Guiding Catheter (aged[1], sterile)		
Test	**Test Method**	**Result**
Physicochemical Profile	USP	Meets requirements
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Hemolysis	ASTM F756	Non-hemolytic.

Sterilization conditions have been validated in accordance with ANSI/AAMI/ISO 11135-1, Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices. The device is sterilized to a SAL of 10^{-6}.

9) Substantial Equivalence

The Heartrail™ III Guiding Catheter (5Fr.) submitted in this 510(k) is substantially equivalent in intended use, design, principle of operation / technology, materials and performance to the Heartrail™ III Guiding Catheter which was cleared under K092372. Differences between the devices do not raise any issues of safety or effectiveness.

[1] (14 weeks at 60°C) Ref: Sterilization Science, *Accelerated Aging of Packaging: Considerations, Suggestions, and Use In Expiration Date Verification.* MD&DI, March 1988, pp.34-39

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL 16 2012

Terumo Medical, Corp.
c/o Mr. Mark Unterreiner
Senior Regulatory Affairs Specialist
950 Elkton Blvd.
Elkton, MD 21921

Re: K113335
Trade Name: Heartrail III Guiding Catheter (5Fr)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II (two)
Product Code: DQO
Dated: June 28, 2012
Received: June 29, 2012

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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosures

Indications for Use

510(k) Number (if known): K113335

Device Name: Heartrail™ III Guiding Catheter (5Fr)

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(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 Devices

510(k) Number K113335