K063618

TenderFlow™Pediatric Arterial Cannula

Submitter Information:
This Premarket Notification is submitted by:

Christina L. Thomas
Telephone: 1-800-262-3304, Ext. 6278

MAR 13 2007

This Premarket Notification is submitted on behalf of:

Terumo Cardiovascular Systems Corporation
6200 Jackson Road
Ann Arbor, Michigan 48103

Device Names:
Proprietary Name: TenderFlow™ Pediatric Arterial Cannula
Common Name: Arterial Cannula
Classification: Arterial Cannulae are classified as Class II devices

Predicate Device:
The unmodified device is identified as Terumo's L Series 1863 Arterial Cannula. This device was originally cleared by FDA with K930620, dated May 8, 1993. This device is legally marketed and has not been the subject of Premarket Notification 510(k) clearance.
The TenderFlow™ Pediatric Arterial Cannula is substantially equivalent in intended use, materials, design, technology, principles of operation, and performance to the predicate (unmodified) Terumo L Series Arterial Cannula.

Intended Use:
The TenderFlow™ Arterial Cannula is indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass procedures. These devices are indicated for up to 6 hours of use.

Principles of Operation and Technology:
The TenderFlow™ Pediatric Arterial Cannula is used in open heart surgery. During open heart surgery blood is drained into a venous cannula just upstream of the heart, at the superior / inferior vena cava and right atrium. The cannula is connected to tubing that routes the blood to a heart / lung machine where the blood is pumped and oxygenated. The blood then continues through this perfusion circuit back to the outlet side of the heart (the patient's aorta), where the blood re-enters the patient's circulatory system via the ascending aorta through an arterial cannulae.

Design and Materials:
The design of the TenderFlow™ Pediatric Arterial Cannula consists of a dip molded, wire reinforced cannula (single-stage) with thin walls and good flow performance. A non-reinforced clamping site is provided adjacent to the connector. The overall length of the cannula from end to end is approximately 9 inches. The distal portion of the spring reinforced body steps up in size both in internal diameter and outside diameter to enhance flow performance. This step-up diameter is approximately four to five French sizes larger than the tip section. The step occurs distal to the insertion portion of the cannula at approximately 1 to 2 inches from the tip. The length of the step increases with the French size.
The tip is integral to the body, is not spring reinforced and is stiffened sufficiently to resist kinking and/or collapse. The pediatric arterial cannula has a ¼" barbed connector in either a vented (with luer cap) or non-vented design. The pediatric arterial cannula also includes an optional introducer with a vent cap. This introducer can be used to stiffen the cannula during insertion and reduce blood loss.

The generic materials used in the TenderFlow™ Pediatric Arterial Cannula are as listed:

- Polyvinyl chloride for the tube
- Stainless steel wire which provides spring reinforcement throughout the body of the cannula
- Rigid PVC and UV cure adhesive for the connector
- ABS for the luer cap
- Silicone vent cap and polypropylene rod for the optional introducer
- Each cannula is printed with a medical grade white ink, pigment color Marabu TPL 970 CDT PN

Performance Evaluations:
The performance of the TenderFlow™ Pediatric Arterial Cannula is substantially equivalent to the performance of the predicate (unmodified) device with regards to pressure drop testing and hemolysis testing. The hemolysis testing compared the unmodified 10 Fr. to the modified 6 Fr. device since these were the two smallest devices in both product families. The 6 Fr. performed equal to or better than the 10 Fr. unmodified device. All test results are available upon request.

Substantial Equivalence Comparison:
The TenderFlow™ Pediatric Arterial Cannula is substantially equivalent to the predicate Terumo L Series Pediatric Arterial Cannula device as follows:

Intended Use:

The TenderFlow™ Pediatric Arterial Cannula and the predicate (unmodified) Terumo L Series Arterial Cannula share the same intended

uses. Both are indicated for perfusion of the aorta during bypass surgery for up to 6 hours of use.

Principles of Operation and Technology: Both the modified and unmodified arterial cannulae are used in open heart surgery to return the oxygenated blood to the patient's ascending aorta.

Design and Materials: The design of the TenderFlow™ Pediatric Arterial Cannula consists of a dip molded, wire reinforced, straight arterial cannula (single-stage) with thin walls, and good flow performance. A non-reinforced clamping site is provided adjacent to the connector. The overall length of the cannula from end to end is approximately 9 inches. The tip is integral to the body, and is not spring reinforced. The tip is stiffened sufficiently to resist kinking. The tip is beveled and tapered.

There are three major differences between the modified and unmodified devices. First, the modified device has the option of a vented connector. Second, the modified device includes an optional introducer system. The other difference is in the length. The unmodified predicate arterial cannula is 7.5 inches in length whereas the modified device is ~9 inches in length.

The design and the materials of the (modified) and the (unmodified) L Series Pediatric Arterial Cannula are essentially the same. Differences include those listed above.

The materials used in the two devices are slightly different. Both use polyvinyl chloride for the tube.
The connector on the modified device uses rigid PVC and UV cure adhesive to bond whereas the unmodified predicate device is a press fit bond. The modified device uses polypropylene and silicone elastomer in the optional introducer system and ABS for the optional luer cap.

Performance: Comparison studies of the performance of the (modified) Pediatric Arterial Cannula and the unmodified predicate L Series Pediatric Arterial Cannula were conducted for pressure drop versus flow rate with water testing and the dynamic hemolysis test because these speak to performance. All other tests listed below were conducted on the modified device only because these speak to device integrity.

- Connector attachment
- Clamp test
- Kink test
- Leak test
- Air venting and priming
- Tensile test
- Simulated use test
- Ship test

- Shelf Life test

These test results showed either no or favorable clinically significant performance differences.

Substantial Equivalence Summary:
In summary, the (modified) TenderFlow™ Pediatric Arterial Cannula and the predicate (unmodified) L Series Pediatric Arterial Cannula are substantially equivalent in intended use, principles of operation and technology, design, and performance. Any noted differences between the devices do not raise new issues of safety and effectiveness.

Additional Safety Information:
- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.
- Post-sterilization release for use will be determined in consideration of maximum Ethylene Oxide, Ethylene Chlorohydrin and Ethylene Glycol (as appropriate) residue limits and maximum levels of patient exposure in accordance with EN ISO 10993-7 and AAMI TIR-19.
- Biocompatibility studies were conducted as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993: 2003, "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.
- Terumo has conducted material characterization studies – including physio-chemical profiles of aged and non-aged devices to demonstrate stability of the materials, and found the materials to be stable over the expiry of the product.

Conclusion:
In summary, the TenderFlow™ Pediatric Arterial Cannula is substantially equivalent in intended use, principles of operation and technology, design and performance to the predicate (unmodified) L Series Terumo Pediatric Arterial Cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2007

Terumo Cardiovascular Systems
c/o Ms. Christina L. Thomas
Sr. Specialist, Regulatory Management
6200 Jackson Road
Ann Arbor, MI 48103

Re: K063618
TenderFlow™ Pediatric Arterial Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DWF
Dated: February 12, 2007
Received: February 16, 2007

Dear Ms. Thomas:

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number (if known):

Device Name: TenderFlow™ Pediatric Arterial Cannula

Indications For Use:

The TenderFlow™ Pediatric Arterial Cannula is a surgically invasive device intended for short term use and indicated for cannulation and perfusion of the ascending aorta during cardiopulmonary bypass surgery.
These devices are indicated for up to 6 hours of use.

Christina Thomas, R.N., B.S.N.
Sr. Regulatory Affairs Specialist
Terumo Cardiovascular Systems

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular
510(k) Number K063618