Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor:	Estech 2603 Camino Ramon Suite 100 San Ramon, CA 94583 Tel: 925-866-7111
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Cardiopulmonary bypass vascular cannula
Device Classification & Code:	Class II, DWF (21 CFR 870.4210)
Device Classification Name:	Cardiopulmonary bypass vascular catheter, cannula or tubing
Device Proprietary Name:	ESTECH Aortic Easy Flow Cannula

Predicate Device Information:

Predicate Devices:	Low Jetting Aortic Arch Cannula (K934127) ESTECH Remote Access Perfusion FV Cannula (K052081)
Predicate Device Manufacturers:	Sarns a division of Terumo ESTECH, Inc.
Predicate Device Common Name:	Cardiopulmonary bypass vascular cannula
Predicate Device Classification:	21 CFR 870.4210
Predicate Device Classification & Code:	Class II, DWF

b. Date Summary Prepared
6 January 2006

c. Description of Device
The Estech Aortic Easy Flow Cannula is a sterile, single-use, device. The single-lumen polymer tube incorporates wire-wrapping with multiple perforations at the distal end to provide a diffuse flow pattern. The barbed proximal end is intended to connect into cardiopulmonary bypass tubing to provide extracorporeal circulation of the blood, most typically during stopped-heart surgical procedures. Each cannula is provided with a flexible obturator to assist with the placement and positioning of the cannula.

d. Intended Use

The ESTECH Aortic Easy Flow Cannula is intended for use in the perfusion of the aorta during cardiovascular surgery procedures requiring extracorporeal cardiopulmonary bypass (CPB) up to 6 hours.

e. Comparison to Predicate Device

The ESTECH Aortic Easy Flow Cannula is identical in intended use, technology, design, to that of the Low Jetting Aortic Arch Cannula (K934127). The ESTECH Aortic Easy Flow Cannula is identical in materials, manufacture, and packaging to the ESTECH Remote Access Perfusion FV Cannula (K052081).

Estech concludes that the ESTECH Aortic Easy Flow Cannula is substantially equivalent to the predicate devices.

f. Summary of Supporting Data

Biocompatibility testing consistent with ISO 11193 is presented in Section 15. The ESTECH Aortic Easy Flow Cannula met the criteria for biocompatibility.

Preclinical performance data was supplied to demonstrate that the ESTECH Aortic Easy Flow Cannula can meet its labeled performance claims, and to demonstrate substantial equivalence with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

Endoscopit Technologies, Incorporated
c/o Mr. Craig Coombs
Coombs Medical Device Consulting
1193 Sherman Street
Alameda, California 94501

Re: K060101
Trade/Device Name: ESTECH Arotic Easy Flow Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: April 17, 2006
Received: April 28, 2006

Dear Mr. Coombs:

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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known):

Device Name: ESTECH Aortic Easy Flow Cannula

Indications For Use:

The ESTECH Aortic Easy Flow Cannula is intended for use in the perfusion of the aorta during cardiovascular surgery procedures requiring extracorporeal cardiopulmonary bypass (CPB) up to 6 hours.

Prescription Use __X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060107