SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Information:

Category	Comments
Sponsor:	Estech 4135 Blackhawk Plaza Circle. Suite 150 Danville, CA 94506 Tel: 925-648-3500
Correspondent:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501
Contact Information:	Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Cardiopulmonary bypass catheter, cannula or tubing
Device Proprietary Name:	Remote Access Perfusion (RAP™) Femoral Venous Cannula
Device Classification Name:	Cardiopulmonary bypass catheter, cannula or tubing, 21 CFR 870.4210
Device Classification & Code:	Class II, DWF

Predicate Device Information:

Predicate Devices:	ULTRAFLEX™ Venous Cannula (K031827) RMI Fem-Flex Femoral Access Cannulation Set (K891576)
Predicate Device Manufacturers:	Medtronic Research Medical Incorporation
Predicate Device Common Name:	Cardiopulmonary bypass catheter, cannula or tubing
Predicate Device Classification:	21 CFR 870.4210
Predicate Device Classification & Code:	Class II, DWF

b. Date Summary Prepared
July 25, 2005

c. Description of Device
The Estech Remote Access Perfusion (RAP™) Femoral Venous Cannula is a sterile, single-use, open-ended, hollow polymer tube with multiple perforations at the distal end. 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.

The RAP FV cannula is provided with a flexible obturator to assist with the placement and positioning of the cannula. It can be guided over a 0.035" guidewire. The RAP FV cannula has a radiopaque obturator and depth markers to assist the physician with placement.

The RAP FV cannula ranges in outside diameter from ~~18~~ 22 – 26 Fr, and in length from 60 – 76 cm.

d. Intended Use

The ESTECH Remote Access Perfusion Femoral Venous Cannula is intended for use as a venous drainage cannula during cardiopulmonary bypass. up To 6 hours.

e. Comparison to Predicate Device

The Estech Remote Access Perfusion (RAP™) Femoral Venous Cannula is substantially equivalent in intended use, technology, design and materials to the predicate devices.

The Estech RAP Femoral Venous Cannula is substantially equivalent to the Medtronic ULTRAFLEX™ Venous Cannula (K031827) and the RMI Fem-Flex Femoral Access Cannulation Set (K891576).

The current and predicate devices are sterile, single use, open-ended, hollow polymer tubes inserted into the vena cava via the femoral vein. They are all intended to be used with cardiopulmonary bypass equipment as venous drainage cannula.

f. Summary of Supporting Data

Biocompatibility testing consistent with ISO 11193 is presented in Section 6. All components of the Estech RAP Femoral Venous Cannula passed the testing.

Preclinical performance data was supplied to demonstrate that the RAP FV 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

DEC 16 2005

Coombs Medical Device Consulting
c/o Mr. Craig Coombs
President
1193 Sherman Street
Alameda, CA 940501

Re: K052081
Remote Access Perfusion (RAP™) Femoral Venous Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Catheter, Cannula or Tubing
Regulatory Class: Class II (Two)
Product Code: DWF
Dated: October 24, 2005
Received: October 26, 2005

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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R Volkmer

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

Enclosure

Indications for Use

510(k) Number (if known): K052081

Device Name: Remote Access Perfusion (RAP™) Femoral Venous Cannula

Indications For Use:

The ESTECH Remote Access Perfusion Femoral Venous Cannula is intended for use as a venous drainage cannula during cardiopulmonary bypass 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)

Diane R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052081