K032632

OCT 2 2 2003

ESTECH

LEAST INVASIVE CARDIAC SURGERY

510(k) Summary

A. Submitter / 510(k) Sponsor:

ESTECH, Inc.
4135 Blackhawk Plaza Circle
Suite 150
Danville, CA 94506
Tel: 925-648-3500
Fax: 925-648-3507
Contact: Arthur Bertolero
Date Prepared: 2002-09-05

B. Device Name:

Remote Access Perfusion Cannula Left Axillary 21 French

Common/Generic Device Name: Cannula
Classification Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass under 21 CFR 870.4210

C. Predicate Device(s)

Predicate Device Name:	ESTECH Remote Access Perfusion Cannula	Axillary Access Arterial Cannula
Manufacturer:	ESTECH	Edwards Lifesciences
510(k) Number:	K990573	K002578
Substantial Equivalence Decision Date:	1999-03-11	2002-04-11

D. Device Description

The ESTECH Remote Access Perfusion Cannula Left Axillary 21 French is a disposable 31 cm long flexible polyurethane tube with three (3) lumens with an inflatable polyurethane balloon at the distal end of the cannula. The inflatable balloon has elastomeric properties designed to provide aortic occlusion in a range of aorta sizes with internal diameters from 22 mm to 34 mm. The outside diameter of the cannula is 21 Fr. (7 mm). The cannula has a central lumen for the delivery of arterial blood through multiple distal outlets at flow rates of 1.0 to 5.0L/min, a lumen that communicates with the aorta in the area of the aortic root for delivery of cardioplegia solution and left ventricle venting, and a small lumen for control of the distal balloon. Radio-opaque arch segment of cannula and insertion depth marks aid in positioning the device.The Cannula are provided sterile in individual packages for single use.

E. Indications for Use

The ESTECH Remote Access Perfusion Cannula Left Axillary 21 French is intended for use in arterial perfusion of the aorta, via axillary artery, in cardiovascular surgery procedures requiring extracorporeal cardiopulmonary bypass (CPB). This device is indicated for short term cardiopulmonary bypass (< 6 hours). The device may also be used to occlude the ascending aorta, deliver cardioplegia solution and vent the aortic root.

F. Summary of Technological Characteristics Comparison

For complete detail regarding comparison of the proposed device with predicate devices please see Section IIb of this 510(k) application. The following table lists the feature comparison of the three devices:

	ESTECH RAP Cannula Left Axillary 21Fr	ESTECH RAP Cannula (Femoral)	Edwards Axillary Access Arterial Cannula
	Intended for use in arterial perfusion via axillary artery	Intended for use in arterial perfusion via femoral artery	Intended for use in arterial perfusion via axillary artery
	Intended for short-term CPB (<6hrs)	Intended for short-term CPB (<6hrs)	Intended for short-term CPB (<6hrs)
	Multi-channel, multi-function integrated cannula	Multi-channel, multi-function integrated cannula	Single-channel, single-function cannula
	Single step insertion	Single step insertion	Single step insertion
	Facilitates Antegrade Blood Flow	Facilitates Antegrade Blood Flow	Facilitates Antegrade Blood Flow
	Low pressure/velocity blood flow system ("soaker hose") via multiple blood outlet ports	Low pressure/velocity blood flow system ("soaker hose") via multiple blood outlet ports	Higher pressure/velocity blood flow system ("nozzle") via single blood outlet port
	Rated for blood flow rates 1.0-5.0L/min	Rated for blood flow rates 1.0-5.0L/min	Rated for blood flow rates 1.0-5.0L/min
	Flat-sided distal aortic occlusion balloon – more anatomical, easier placement, better stability	Flat-sided distal aortic occlusion balloon – more anatomical, easier placement, better stability	No aortic clamping. Perfusion only.
	Designed to provide aortic occlusion in a range of aorta sizes with internal diameters from 22 mm to 34 mm	Designed to provide aortic occlusion in a range of aorta sizes with internal diameters from 22 mm to 34 mm	No aortic clamping. Perfusion only.
	Usable Length = 31cm (designed for axillary	Usable Length = 81cm (designed for femoral	Usable Length = 33 cm (designed for axillary

	Outside diameter of the cannula is 21 Fr. (7 mm)	Outside diameter of the cannula is 21 Fr. (7 mm)	Outside diameter of the cannula is 22 Fr. (7.3 mm)
	Advanced over guidewire to insure accurate placement	Advanced over guidewire to insure accurate placement	Does not advance over guidewire
	Internal obturator to prevent kinking	Internal obturator to prevent kinking	Wire-wrapped to prevent kinking
	Radio-opaque arch segment of cannula and insertion depth marks aid in positioning the device	Radio-opaque arch segment of cannula and insertion depth marks aid in positioning the device	No radio-opaque materials or insertion depth marks
	Delivers cardioplegia and facilitates aortic root venting	Delivers cardioplegia and facilitates aortic root venting	No cardioplegia delivery or venting. Perfusion only.
	Provided sterile. Single use device.	Provided sterile. Single use device.	Provided sterile. Single use device.
	On-site customized training	On-site customized training	Unknown training program

G. Summary of Non-Clinical Performance Data

The laboratory testing adhered to Good Laboratory Practices guidlelines. All test protocols and results can be found in Section III Device Specifications of this 510(k) applications. Below is a bried summary of tests conducted.

The occlusion balloon has been tested to demonstrate that it meets performance and safety specifications as follows:

Occlusion Balloon Restricted Burst Test: This test was performed to characterize the inflation characteristics of the balloon up to burst in a restricted environment. The pressure data as a function of inflation volume were collected.

Occlusion Balloon Volume/Pressure/Diameter: This test was performed to characterize the inflation characteristics of the balloon up to burst. The pressure and diameter data as a function of inflation volume were collected.

Occlusion Balloon Repeat Inflation Test: This test was performed to demonstrate that the balloon can be inflated repeatedly if necessary.

Occlusion Balloon Sustained Inflation Test: This test was performed to demonstrate that the balloon can withstand at least 6 hours if inflation.

Hemolysis Testing: This test was performed to evaluate the cellular damage produced by the system when used during the cardiac bypass procedures. Due to the

fact that all cardiac bypass procedures produce some degree of hemolysis which may be at least partially compensated for in human and animal testing, an in-vitro test was used to evaluate the relative effect of the device in the circuit as compared to the predicate devices.

Flow Testing: The pressure drop across the cannula was measured for a range of arterial perfusion flow rates from 0-5 liters per minute and was within specification. Minimum cardioplegia delivery flow rates for a given pressure were also within specification.

Biocompatibility Testing: Biocompatibility testing has been completed for the currently marketed predicate device, ESTECH Remote Access Perfusion Cannula. All materials used in the manufacture of the current device are identical and thus testing will not be repeated.

Animal Testing: Animal testing was conducted to demonstrate that the device was suitable for its intended use in terms of insertion via axillary artery and placement. Performance of the device, including the occlusion balloon and perfusion/cardioplegia flow, are known to be safe and effective for its intended use as these features have either remained unchanged from the predicate device or have been demonstrated to be adequate based on the tests described above.

H. Substantial Equivalence Summary

The proposed device is an adaptation of the currently marketed remote access perfusion cannula, designed for femoral artery access. The only design changes to the current device included reducing the length of the cannula to facilitate insertion via axillary artery and changing the outlet blood port configuration to suit the new length of the device.

The proposed device has a modified indication for use statement. The new indication, for arterial perfusion by cannulation of the axillary artery, versus femoral artery, does not change the intended use of the device, which is arterial perfusion during cardiopulmonary bypass. The proposed device, therefore is substantially equivalent to the predicate device in intended use.

ESTECH has demonstrated through its comparison of characteristics with predicate device and comparison of performance testing with predicate device that the Remote Access Perfusion Cannula LA 21 Fr is substantially equivalent to the predicate device in technology, material, manufacture and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2003

ESTECH, Inc.
c/o Mr. Arthur Bertolero
4135 Blackhawk Plaza Circle, Suite 150
Danville, CA 94506

Re: K032632
Remote Access Perfusion Cannula Left Axillary 21 French
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: August 25, 2003
Received: August 29, 2003

Dear Mr. Bertolero:

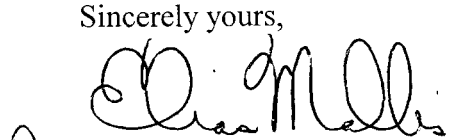
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4648. 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,



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

Enclosure

ESTECH

LEAST INVASIVE CARDIAC SURGERY

510(k) Number (if known): K032632

Device Name: Remote Access Perfusion Cannula Left Axillary 21 French

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANTOHER 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 Devices

510(k) Number K032632