

510(k) Summary**ESTECH Arterial Remote Access Perfusion Cannula**

Common/Classification Name: Cardiopulmonary Bypass vascular catheter, cannula or tubing as classified under 21 CFR 870.4210

ESTECH
4115 Blackhawk Plaza Circle, Suite 100
Danville, CA 94506
925-648-2033 (Tel), 925-648-2034 (Fax)

Prepared: February 19, 1999

A. Legally Marketed Predicate Device

The ESTECH Arterial Remote Access Perfusion Cannula is substantially equivalent to perfusion cannulae currently marketed in the U.S. The ESTECH cannula is specifically equivalent to the Heartport Arterial Perfusion System. Both systems have the same intended use, which is to provide arterial perfusion of the aorta, via a femoral artery, in cardiovascular surgery procedures requiring extracorporeal cardiopulmonary bypass. Both systems provide occlusion of the ascending aorta with an inflatable balloon and may be used for delivery of cardioplegia through an internal lumen of the device. Additional similarities between the ESTECH Arterial Perfusion Cannula and the Heartport Cannula are the ability to monitor Aortic Root Pressure and the capability to provide Left Ventricle Venting. The ESTECH cannula is 21 French in diameter and the Heartport system is offer in 21 and 23 French diameters.

The primary difference between the systems is that the Heartport Arterial Perfusion System requires the use of the Femoral Artery Cannula and an Aortic Occlusion cannula, which must be inserted through the Femoral Artery Cannula. These functions are combined in the single device ESTECH Arterial Remote Access Perfusion Cannula. The ESTECH device delivers blood into the Aorta "Antegrade Flow" and the Heartport device delivers blood into the femoral artery "Retrograde Flow".

B. Device Description

The ESTECH Arterial Remote Access Perfusion Cannula is a sterile, disposable, flexible polyurethane tube with three integrated lumens and an inflatable polyurethane balloon at the distal end of the cannula. The outside diameter of the cannula is 21 French. The cannula has a central lumen for delivery of arterial blood through multiple distal outlets at a flow rate up to 5 liters per minute, a small lumen for delivery of cardioplegia or venting at the aortic root, and an additional smaller lumen for control of the distal balloon. The blood outlet ports are multiple elongated openings along the cannula proximal to the occlusion balloon. Radiopaque balloon markers and insertion depth marks aid in positioning the device. The cannulas are provided sterile in individual packages for single use.

C. Indications for Use

The ESTECH Arterial Remote Access Perfusion Cannula is intended for use in arterial perfusion of the aorta, via a femoral artery, in cardiovascular surgery procedures requiring extracorporeal cardiopulmonary bypass (CPB). The device may also be used to occlude the ascending aorta, deliver cardioplegia solution and vent the aortic root.

D. Substantial Equivalence Summary

The ESTECH Arterial Remote Access Perfusion Cannula has the same intended use as the 510(k) cleared Heartport Perfusion System. Both systems provide arterial perfusion of the aorta, via a femoral artery, in cardiovascular surgery procedures requiring extracorporeal cardiopulmonary bypass.

The primary difference is that the Heartport Arterial Perfusion System requires the use of a Femoral Artery Cannula and an Aortic Occlusion cannula, which must be inserted through the Femoral Artery Cannula. These functions are combined in the single device ESTECH Perfusion Cannula to simplify the procedure.

Another difference is the perfusion flow pattern of each system. The multiple holes along the length of the ESTECH cannula produce a normal antegrade flow pattern similar to physiological conditions of flow. Heartport produces retrograde flow from a single outlet port of the Heartport femoral cannula. Testing was performed to demonstrate that the ESTECH cannula does not induce a higher degree of hemolysis or pressure drop than expected during bypass procedures.

All materials used in the ESTECH cannula have a safe history of use in medical devices and are used by the manufacturer to produce similar 510(k) cleared devices.

The ESTECH Arterial Remote Access Perfusion Cannula is therefore substantially equivalent to currently marketed devices.

E. Technological Characteristics

See Device Description, above.

F. Testing

The laboratory testing adhered to Good Laboratory Practices guidelines.

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

Occlusion Balloon Volume/Pressure/Diameter: This test was performed to document 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 Inflation Hold Test: This test was performed to demonstrate that the balloon can withstand at least 6 hours of inflation.

Hemolysis Testing: This test was performed to evaluate the cellular damage produced by the system when used during cardiac bypass procedures. Since all cardiac bypass procedures produce some degree of hemolysis which may be at least partially compensated for in human or animal testing, an in vitro test was used to evaluate the relative effect of the ESTECH cannula in the circuit.

Flow Testing: The pressure drop was measured for a range of arterial perfusion flow rates of 0-5 liters per minute. In additional testing, the pressure/flow characteristics of the Heartport cannula were measured. While the pressure drop was determined to be within ESTECH specifications, the outlet blood velocity of the Heartport device was determined to be unacceptable.

Biocompatibility Testing: Biocompatibility Testing was performed on all critical components of the Cannula to verify biocompatibility.

Animal Testing: Animal studies of the ESTECH Arterial Remote Access Cannula to evaluate the handling characteristics and to verify performance of all intended functions. The ESTECH perfusion cannula was used in all functional modes. The conclusion of this study was that complete function of the ESTECH Arterial Remote Access Perfusion Cannula and ease of use were demonstrated.

Clinical Investigation: A Clinical Investigation was conducted to verify the safety, efficacy, and performance of the device.

G. Conclusions

ESTECH has demonstrated through its comparison of characteristics with predicate device and comparison of performance testing with the predicate device that the ESTECH Arterial Remote Access Perfusion Cannula is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 1999

Mr. Arthur A. Bertolero
Estech, Inc.
4115 Blackhawk Plaza Circle,
Suite 100
Danville, CA 94506

Re: K990573
Estech Arterial Remote Access Perfusion Cannula
Regulatory Class: II (Two)
Product Code: 74 DXC, 74 DWF
Dated: February 22, 1999
Received: February 23, 1999

Dear Mr. Bertolero:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Arthur A. Bertolero

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990573

Device Name: ESTECH Arterial Remote Access Perfusion Cannula

Indications for Use:

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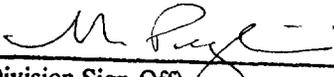
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number _____