K091542

Section 5: 510(k) Summary of Safety and Effectiveness

OCT 20 2009

Device Information:

Category	Comments
Sponsor:	ESTECH, Inc. 2603 Camino Ramon Suite 100 San Ramon, CA 94583 Tel: 925-543-2110
Correspondent:	Tamer Ibrahim Vice President, R&D, QA/RA 2603 Camino Ramon San Ramon, CA 94523
Contact Information:	Tel: 925-543-2110 Fax: 925-866-7117
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 EasyFlow Cannula with Guidewire

Predicate Device Information:

Predicate Device:	ESTECH Aortic EasyFlow Cannula **(K060101)**
Predicate Device Manufacturer:	ESTECH, Inc.
Predicate Device Common Name:	Cardiopulmonary bypass vascular cannula
Predicate Device Classification:	21 CFR 870.4210
Predicate Device Classification & Code:	Class II, DWF

Predicate Device:	Medtronic EOPA Elongated One-Piece Arterial Cannula with Guidewire (K000274)
Predicate Device Manufacturer:	Medtronic, Inc.
Predicate Device Common Name:	Cardiopulmonary bypass vascular cannula
Predicate Device Classification:	21 CFR 870.4210
Predicate Device Classification & Code:	Class II, DWF

Predicate Device:	Edwards Lifesciences Venous Flex II Peripheral And Intra-Operative Access Venous Return Cannulae (K974259)
Predicate Device Manufacturer:	Edwards Lifesciences, Inc.
Predicate Device Common Name:	Cardiopulmonary bypass vascular cannula
Predicate Device Classification:	21 CFR 870.4210

Predicate Device Classification & Code:	Class II, DWF

Predicate Device:	ESTECH Percutaneous Insertion Dilator Kit (K070749)
Predicate Device Manufacturer:	ESTECH, Inc
Predicate Device Common Name:	Vessel dilator for percutaneous catheterization
Predicate Device Classification:	21 CFR 870.1310
Predicate Device Classification & Code:	Class II, DRE

b. Date Summary Prepared

19May09

c. Description of Device

The ESTECH EasyFlow Cannula with Guidewire is a sterile, single-use device. The single-lumen wire reinforced polymer tube incorporates 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 and an optional stylet which inserts into the obturator to provide additional column strength for insertion. The product also comes with a 0.035" diameter guidewire, up to 3 vessel dilators, an 18 gauge needle, and scalpel for introduction

d. Intended Use

The ESTECH EasyFlow Cannula with Guidewire is intended for use with cardiopulmonary bypass as an arterial return or venous drainage cannula for up to 6 hours.

e. Comparison to Predicate Device

The ESTECH EasyFlow Cannula with Guidewire is identical in technology, design, materials, manufacture, and packaging to the ESTECH Aortic EasyFlow Cannula (K060101) with the addition that it is packaged with a guidewire and accessory introduction components including scalpel, needle, and dilators. A small hole has been added to the cannula and obturator tips to facilitate pass through of the guidewire. The ESTECH EasyFlow Cannula with Guidewire is similar in intended use to the Medtronic EOPA Elongated One-Piece Arterial Cannula with Guidewire that it is intended for use with cardiopulomonary bypass as an arterial return cannula. The ESTECH EasyFlow Cannula with Guidewire is similar in intended use to the Edwards Lifesciences Venous Flex II Peripheral

And Intra-Operative Access Venous Return Cannulae which are intended for use in situations in which short term cardiopulmonary bypass peripheral access venous return procedures, i.e., internal jugular vein, right innominate vein, and femoral vein access, as well as the standard intra-operative access venous return procedures, i.e right atrial appendage and right atriotomy access is desired.

ESTECH concludes that the ESTECH EasyFlow Cannula with Guidewire is substantially equivalent to the predicate devices.

f. Summary of Supporting Data

Biocompatibility analysis demonstrates that the device is in compliance with ISO 10993

Bench testing has demonstrated that the device meets the proposed product specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 20 2009

Endoscopic Technologies, Inc.
c/o Mr. Tamer Ibrahim
Vice President
2603 Camino Ramon, Suite 100
San Ramon, CA 94583

Re: K091542
ESTECH EasyFlow Cannula with Guidewire
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DWF
Dated: September 21, 2009
Received: September 23, 2009

Dear Mr. Ibrahim:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

510(k) Number (if known): K091542

Device Name: ESTECH EasyFlow Cannula with Guidewire

Indications For Use:

The ESTECH EasyFlow Cannula with Guidewire is intended for use with cardiopulmonary bypass as an arterial return or venous drainage cannula for 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)

Division of Cardiovascular Devices

510(k) Number K091542