Section 5: 510(k) Summary

Device Information:

Category	Comments
Sponsor:	Estech 4135 Blackhawk Plaza Circle. Suite 150 Danville, CA 94506 Tel: 925-648-3500
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 cardiotomy return sucker
Device Classification & Code:	Class II, DTS (21 CFR 870.4420)
Device Classification Name:	Sucker, Cardiotomy Return, Cardiopulmonary Bypass
Device Proprietary Name:	Estech Clearview™ MV Atrial Depressor

Predicate Device Information:

Predicate Devices:	California Medical Laboratories Rigid Tip Suction Wands (K982891) IBC Cardiac Suction Wand (K963756)
Predicate Device Manufacturers:	California Medical Laboratories International Biophysics Corporation
Predicate Device Common Name:	Cardiopulmonary bypass cardiotomy return sucker
Predicate Device Classification:	21 CFR 870.4420
Predicate Device Classification & Code:	Class II, DTS

b. Date Summary Prepared
13 January 2006

c. Description of Device
The Estech Clearview™ MV Atrial Depressor is a sterile, single use, surgical instruments intended for the collection of blood and other fluids from the surgical field for return through the cardiotomy system during open heart surgery. The a molded polymer proximal connector is intended to connect into cardiopulmonary bypass system to return blood and fluids into the extracorporeal circulation circuit, most typically during stopped-heart surgical procedures.

The Estech Clearview™ MV Atrial Depressor has an integrated shaft designed to connect to the Estech Small Incision Retractor. The retractor creates access to the surgical field

via thoracotomy or mini-sternotomy. When mounted to the retractor, the Estech Clearview™ MV Atrial Depressor can also be used to retract tissues while collecting fluids.

d. Intended Use

The ESTECH Clearview™ MV Atrial Depressor is intended to remove excess fluids from the surgical field for filtering and return to the patient during cardiopulmonary bypass of up to 6 hours. It can also be used to retract tissue to increase visibility.

e. Comparison to Predicate Device

The Estech Clearview™ MV Atrial Depressor is substantially equivalent in intended use, technology, design and materials to the predicate devices.

The Estech Clearview™ MV Atrial Depressor is substantially equivalent to the California Medical Laboratories Rigid Tip Suction Wands (K982891) and the IBC Cardiac Suction Wand (K963756).

The current and predicate devices are sterile, single use, surgical instruments intended for the collection of blood and other fluids from the surgical field for return through the cardiotomy system during open heart surgery.

f. Summary of Supporting Data

Biocompatibility testing consistent with ISO 10993 is presented in Section 15. All components of the Estech Clearview™ MV Atrial Depressor passed the testing.

Preclinical performance data was supplied to demonstrate that the Estech Clearview™ MV Atrial Depressor can meet its labeled performance claims, and to demonstrate substantial equivalence with the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2006

Coombs Medical Device Consulting
c/o Mr. Craig Coombs
President
1193 Sherman Street
Alameda, CA 94501

Re: K053021
ESTECH Clearview™ MV Atrial Depressor
Regulation Name: Cardiopulmonary Bypass Cardiotomy Return Sucker
Regulatory Class: II
Product Code: DTS
Dated: January 10, 2006
Received: January 12, 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 (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. Lichner

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

Enclosure

K053021

Section 4: Indications for Use Statement

510(k) Number (if known): K053021

Device Name: ESTECH Clearview™ MV Atrial Depressor

Indications For Use:

The ESTECH Clearview™ MV Atrial Depressor is intended to remove excess fluids from the surgical field for filtering and return to the patient during cardiopulmonary bypass of up to 6 hours. It can also be used to retract tissue to increase visibility.

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)

Page 1 of 1

Donna R Vechman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053021