K972503

Summary of Safety and Effectiveness

AUG 26 1997

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The California Medical Laboratories, Inc. devices are substantially equivalent to the DLP and Research Medical predicate device. The California Medical Laboratories, Inc. devices have substantially equivalent intended uses as the predicate device. The California Medical Laboratories, Inc. devices have technologic characteristics which are substantially equivalent to the DLP and Research Medical predicate device.

COMPANY AND CONTACT PERSON

California Medical Laboratories Inc.
2681 Kelvin Avenue
Irvine, California 92714

Mehmet Bicakci
President

DEVICE NAME

California Medical Laboratories Inc. Vessel Cannula with and without wing and with and without check valve, Aortic Root Cannula with and without Vent Line, Cardioplegia "Y" Perfusion Adapter, Cardioplegia "Y" Recirculation Adapter, Cardioplegia Straight Adapter, Cardioplegia "Y" Venting Adapter.

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

The claim of substantial equivalence is based upon the following devices:

- Research Medical, Inc. Vasoplegia Cannula (K 896778) designed for the delivery of cardioplegia solution to the heart during cardipulmonary bypass surgery,
- DLP, Inc. Aortic Root Cannula (K790565) with and without a vent line designed for the delivery of cardioplegia solution and venting the left heart during cardiopulmonary bypass surgery,
- DLP, Inc. "Y" Adapter-Coronary Perfusion (K791498) is designed for delivery of cardioplegia solution during cardiopulmonary bypass surgery.
- DLP, Inc.Straight Adapter (K790564) is designed for use during cardiopulmonary bypass surgery for connecting a cannula or catheter to an administration or vent line.
- DLP, Inc. "Y" Adapters (K790563) is designed for use during cardiopulmonary bypass surgery to deliver cardioplegia solution and vent the heart.

DESCRIPTION OF DEVICE

The Vessel Cannula is indicated for use in the delivery of cardioplegia solution during cardiopulmonary bypass surgery or to perfuse a vein graft or access the patency in a harvested vein which will be used for a graft. The Vessel Cannula is a flexible, tapered, polyvinyl chloride tube with a soft distal tip. The distal tip is composed of two sizes of anchor hubs (3mm distal-3.6mm proximal) designed to accommodate vessels of various diameters. The proximal female luer-lock is designed to securely connect with a standard cardioplegia delivery line. The cannula is available with or without wings and with or without a check valve.

The Aortic Root Cannula is designed to deliver cardioplegia solution during cardiopulmonary bypass surgery. The cannula consists of flexible polyvinyl chloride tubing with a movable sew ring attached to a soft distal tip. The distal tip has a flange with four suture holes. An introducer needle assembly is provided to facilitate entry into the aorta.

The Cardioplegia Straight Adapter is indicated during cardiopulmonary bypass surgery for connecting a cannula or catheter to an administration and or a vent line. The straight adapter consists of flexible polyvinyl tubing, and connecting adapters in a straight configuration.

The Cardioplegia "Y" Venting Adapter is designed to be used in conjunction with cardiopulmonary bypass surgery to deliver cardioplegia solution, and venting the left heart. It may also be used as an extension line by itself. The adapter consists of flexible polyvinyl chloride tubing, "Y" connector, tubing clamps, and connecting adapters in a "Y" configuration.

The Cardioplegia "Y" Recirculation Adapter is indicated for use for recirculation of cardioplegia solution during cardiopulmonary bypass surgery, to keep the cardioplegia solution at constant temperature. The "Y" recirculation adapter consists of a flexible polyvinyl chloride tubing, "Y" connector, tubing clamps and connecting adapters in a "Y" configuration.

The Cardioplegia "Y" Perfusion Adapter is indicated for use in delivery of cardioplegia solution during cardiopulmonary bypass surgery. The perfusion adapter consists of polyvinyl chloride tubing, tubing clamps, "Y" connector, and connecting adapters in a "Y" configuration.

STATEMENT OF INTENDED USE

The vessel cannula will be supplied with a wing or without a wing, with or without a check valve to deliver cardioplegia solution to the heart during cardiopulmonary bypass surgery and to perfuse a vein graft or access the patency of the vessel to be used as a graft during cardiopulmonary bypass surgery.

The aortic root cannula is designed to deliver cardioplegia solution during cardiopulmonary bypass surgery and aspirate air from the aorta at the end of the cardiopulmonary bypass surgery. The aortic root cannula with vent line is designed to deliver cardioplegia solution and vent the heart during cardiopulmonary bypass surgery.

The cardioplegia "Y" perfusion adapter is designed for use with the aortic root cannula and vessel cannula to deliver cardioplegia solution during cardiopulmonary bypass surgery. The cardioplegia "Y" recirculation adapter is designed for use for recirculating of cardioplegia solution during cardiopulmonary bypass surgery. The cardioplegia straight adapter is designed for use during cardiopulmonary bypass surgery for connecting a cannula or catheter to an administration or vent line. The cardioplegia "Y" venting adapter is designed for use during cardiopulmonary bypass surgery to deliver cardioplegia solution and vent the left heart.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The predicate devices have the same intended use as stated above.

STATEMENT OF COMPARISON OF TECHNOLOGIC CHARACTERISTICS BETWEEN DEVICE AND PREDICATE DEVICE

The California Medical Laboratories, Inc devices have technologic characteristics which are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Mehmet Bicakci
President
California Medical Laboratories, Inc.
2681 Kelvin Avenue
Irvine, California 92714

AUG 26 1997

Re: K972503
Cardioplegia Adapters, Vessel Cannulae, and Aortic Root Cannulae
Regulatory Class: II (two)
Product Code: 74 DWF
Dated: July 2, 1997
Received: July 3, 1997

Dear Mr. Bicakci:

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 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.

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" (21 CFR 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/dsmamain.html."

Sincerely yours,

Thomas J. Callahan

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

Enclosure

876.4210 - DWF II - CPB Vascular Catheter, Cannula, or Tubing

510(k) Number (if known): K972503

Device Name: California Medical Laboratories Inc. Vessel Cannula with and without wing and with and without check valve, Aortic Root Cannula with and without Vent Line, Cardioplegia "Y" Perfusion Adapter, Cardioplegia "Y" Recirculation Adapter, Cardioplegia Straight Adapter, Cardioplegia "Y" Venting Adapter.

Indications For Use: The vessel cannula will be supplied with a wing or without a wing, with or without a check valve to deliver cardioplegia solution to the heart during cardiopulmonary bypass surgery and to perfuse a vein graft or access the patency of the vessel to be used as a graft during cardiopulmonary bypass surgery.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972503

Prescription Use X **OR** **Over-The-Counter Use** _____
Per 21 CFR 801.109