

## Summary of Safety and Effectiveness

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The California Medical Laboratories, Inc. devices are substantially equivalent to the Baxter 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 Baxter Research Medical predicate device.

COMPANY AND CONTACT PERSON

California Medical Laboratories Inc.  
2681 Kelvin Avenue  
Irvine, California 92614

Mehmet Bicakci  
President

DEVICE NAME

California Medical Laboratories Inc. Antegrade/Retrograde Perfusion Adapter, Antegrade/Retrograde Perfusion Adapter with Pressure Line

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

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

- Baxter Research Medical, Inc. Cardioplegia Antegrade-Retrograde Solution Infusion with or without Retrograde Pressure Monitoring

DESCRIPTION OF DEVICE

The Antegrade/Retrograde Perfusion Adapters are designed to deliver cardioplegia solution to either the coronary sinus or aortic root by the turn of a stopcock and are available with or without a pressure monitoring line. The model with a pressure monitoring line allows for simultaneous monitoring of the coronary sinus pressure while administering cardioplegia solution to either the coronary sinus or aortic root.

In general, a red color-coded tubing with a standard male luer connector connects to the aortic root cannula's infusion port while a blue color-coded tubing with a standard male luer connector connects to the coronary sinus cannula's infusion port for delivery of cardioplegia solution. The model provided with a pressure monitoring line is connected to the pressure monitoring outlet of the coronary sinus cannula at one end and the other end is connected to a transducer via a female luer-lock connector. An optional male luer-lock swivel adapter is also supplied for this connection. The cardioplegia inlet tubing, which is white color-coded in the pressure monitoring line model, connects to the cardioplegia administration line. The adapter also has a base plate, which allows for either suturing or clamping of the stopcock to the surgical drape.

STATEMENT OF INTENDED USE

The Antegrade/Retrograde Perfusion Adapter is indicated for use to deliver cardioplegia solution to either the aortic root or coronary sinus. The Antegrade/Retrograde Perfusion adapter with Pressure Line is indicated for use to deliver cardioplegia solution to either the aortic root or coronary sinus while continually monitoring the pressure of the coronary sinus.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The predicate device has 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

FEB 8 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Mehmet Bicakci  
President  
California Medical Laboratories, Inc.  
2681 Kelvin Avenue  
Irvine, CA 92614

Re: K993818  
Trade Name: Antegrade/Retrograde Perfusion Adapter (CA-80010)  
and Antegrade/Retrograde Perfusion Adapter with  
Pressure Line (CA-81010)  
Regulatory Class: II (two)  
Product Code: DWF  
Dated: November 8, 1999  
Received: November 10, 1999

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 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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

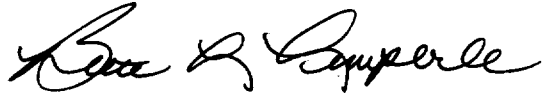
Page 2 - Mr. Mehmet Bicakci

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), or 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,



Celia M. Witten, Ph.D., M.D.  
Acting Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) Number (if known):

Device Name: California Medical Laboratories Inc. Antegrade/Retrograde Perfusion Adapters with or without a Pressure Line

**Indications**

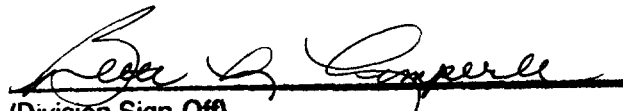
For Use: The Antegrade/Retrograde Perfusion Adapter is indicated for use to deliver cardioplegia solution to either the aortic root or coronary sinus. The Antegrade/Retrograde Perfusion Adapter with Pressure Line is indicated for use to deliver cardioplegia solution to either the aortic root or coronary sinus while continually monitoring the pressure of the coronary sinus.

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X    
801.109

OR Over-The-Counter Use \_\_\_\_\_ Per 21 CFR

  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number   K993818