IV. 510(k) Summary

A. *Submitter / 510(k) Sponsor*

John W. Smith, Manager of Regulatory Affairs

Baxter Research Medical, Inc.
6864 South 300 West
Midvale, Utah 84047
USA

Phone (801) 565-6213

Fax (801) 565-6161

B. *Device Name*

Peripheral Retrograde Cardioplegia Cannula, PRC-012-MIB

Classified by FDA under 21 CFR § 870.4210, *Cardiopulmonary bypass vascular catheter, cannula, or tubing.*

C. *Predicate Devices*

Predicate Device A:	Retroplegia Cannula, RC-014-MIB
Manufacturer:	Baxter Research Medical, Inc. (BRMI)
510(k) Number:	K880103

Predicate Device B:	Heartport Endosinus Catheter
Manufacturer:	Heartport, Inc.
510(k) Number:	K961270

D. *Device Description*

The BRMI Peripheral Retrograde Cannula is a triple lumen radiopaque cannula. The distal tip contains multiple infusion holes and a separate pressure monitoring lumen that terminates at a 3-way stopcock.

A soft, low-pressure, manually inflated and deflated silicone occlusion balloon surrounds the distal body (proximal to the flow holes).

The cannula has approximately 50cm of usable lumen length.

Each Peripheral Retrograde Cannula is individually packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

E. *Intended Use*

The Peripheral Retrograde Cardioplegia Cannula is indicated for use in the delivery of blood or cardioplegic solution.

Placement of the cannula may be performed either through the jugular vein or intraoperatively.

F. *Summary of Comparison, Proposed and Predicate Devices*

The proposed device is substantially equivalent to the cited predicate devices in intended use, technology, materials, and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1999

Mr. John W. Smith
Manager, Regulatory Affairs
Baxter Healthcare Corporation
6864 South 300 West
Midvale, UT 84047-1051

Re: K983791
Peripheral Retrograde Cardioplegia Cannula
Regulatory Class: II (Two)
Product Code: DWF
Dated: March 23, 1999
Received: March 25, 1999

Dear Mr. Smith:

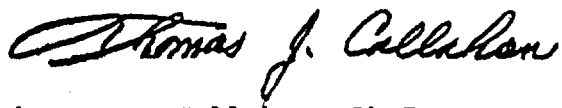
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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

D. Indications for Use Statement

510(k) Number (if known): K983791

Device Name: Peripheral Retrograde Cardioplegia Cannula

Indications for use:

The Peripheral Retrograde Cardioplegia Cannula is indicated for use in the delivery of blood or cardioplegic solution.

Placement of the cannula may be performed either through the jugular vein or intraoperatively.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983791

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)