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. *Date Prepared*

1999-06-30

C. *Device Name*

Retrograde Cardioplegia Cannula with Duraflo Treatment, DII-RC-014

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

D. *Predicate Devices*

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

Predicate Device B:	Extracorporeal Circuit with Duraflo II Heparin Treatment
Manufacturer:	Baxter Healthcare Corporation
510(k) Number:	K932208

E. *Device Description*

The Baxter Research Medical Retrograde Cardioplegia Cannula with Duraflo Treatment is a dual lumen cannula. The distal tip contains multiple infusion holes and an opening into the separate pressure monitoring lumen. A soft, low-pressure, self-inflating balloon surrounds the distal body (proximal to the flow holes). Inflation is accomplished via the differential pressure that occurs within the cannula during infusion. The balloon will deflate spontaneously when flow is stopped. The cannula is furnished with an introducer stylet. Each device is individually packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

The device is treated with Baxter Healthcare Corporation's proprietary Heparin coating, Duraflo.

F. *Intended Use*

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

Extracorporeal circuit components with the Duraflo treatment are indicated for use in cardiopulmonary surgery when a heparin-treated blood path is desired.

G. *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.

The proposed device consists of a device **identical to** the device cited as predicate Device A, which has been treated with the Duraflo treatment included in Predicate Device B.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1999

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

Re: K991170
Retrograde Cardioplegia Cannula with Duraflo Treatment
Regulatory Class: II (Two)
Product Code: DWF
Dated: April 6, 1999
Received: April 7, 1999

Dear Mr. Smith:

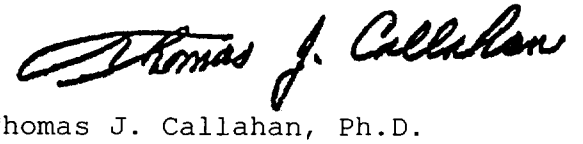
We have reviewed your Section 510(k) notification of intent to market the Retrograde Cardioplegia Cannula with Duraflo Treatment, Model Number DII-RC-014, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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), promotion, or advertising, 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/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): K991170

Device Name: Retrograde Cardioplegia Cannula with Duraflo Treatment

Indications for use:

The Retrograde Cardioplegia Cannula with Duraflo Treatment is indicated for use in the delivery of blood or cardioplegic solution intraoperatively.

Extracorporeal circuit components with the Duraflo treatment are indicated for use in cardiopulmonary surgery when a heparin-treated blood path is desired.

This device is for short-term use only (< 6 h).

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991170

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)