

APPENDIX X Summary of Safety and Efficacy

JUL 7 1998

510(k) Summary

A. NAME & ADDRESS OF CONTACT PERSON

Larry Wood
Baxter Healthcare Corporation
CardioVascular Group
Edwards CVS Division
17221 Red Hill Avenue
Irvine, CA 92614-5686

B. DEVICE NAME

1. Carpentier-Edwards Classic™ Ring with Duraflo® Treatment, Models 4425 and 4525
2. Carpentier-Edwards Physio® Annuloplasty Ring with Duraflo® Treatment, Model 4475
3. Cosgrove-Edwards® Annuloplasty System with Duraflo® Treatment, Model 4625

C. PREDICATE DEVICE NAME

1. Carpentier-Edwards® Classic™ Annuloplasty Ring, Models 4400 and 4500.
2. Carpentier-Edwards Physio® Annuloplasty Ring, Model 4450
3. Cosgrove-Edwards® Annuloplasty System, Model 4600

D. DEVICE DESCRIPTION

1. The Carpentier-Edwards Classic™ Ring with Duraflo® Treatment (Models 4425 and 4525) is constructed of titanium alloy and has a sewing ring margin that consists of a layer of siloxane polymer rubber covered with a polyester knit fabric.

The mitral ring, Model 4425, conforms to the configuration of a normal mitral orifice. It is kidney-shaped with one long curved segment corresponding to the posterior leaflet. The ring is open in the rectilinear portion corresponding to the anterior leaflet and has transverse colored threads indicating the anterior and posterior commissures.

The oval tricuspid ring, Model 4525, conforms to the configuration of a normal tricuspid orifice. The ring has one rectilinear segment corresponding to the septal leaflet and one long curved segment corresponding to the anterior and posterior leaflets. The ring is open at the anteroseptal commissure. Transverse colored threads indicate the site of the anteroposterior and posteroseptal commissures.

2. The Carpentier-Edwards Physio® Annuloplasty Ring with Duraflo® Treatment, Model 4450, is constructed of Elgiloy® bands separated by polyester film strips and has a sewing ring margin that consists of a layer of siloxane polymer tubing covered with a woven polyester cloth.
3. The Cosgrove-Edwards® Annuloplasty System with Duraflo® Treatment, Model 4600, is composed of a silicone rubber strip compounded with barium sulfate to improve radiographic visualization. This silicone rubber strip is covered with woven polyester velour cloth wrapped around the silicone and sewn together with a single seam using polyester thread.

E. INTENDED USE

The intended use of Baxter's annuloplasty ring products with Duraflo® Treatment has not changed from the predicate devices. Annuloplasty rings are intended for use in patients to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.

F. TESTING SUMMARY

The following studies were conducted to qualify Baxter's annuloplasty ring product lines with Duraflo® Treatment and 100% EO Sterilization.

- Material Components Evaluation
- Biocompatibility Testing
- Packaging Integrity Testing
- Validation of 100% Ethylene Oxide Sterilization
- Heparin Leachout Studies
- Animal Data

All testing conducted showed no adverse effects of the Duraflo®-treated annuloplasty rings undergoing 100% EO sterilization, resulting in a safe product for use in an implantable application.

G. SUBSTANTIAL EQUIVALENCE SUMMARY

The claim of substantial equivalence between the predicate and proposed devices is based on the following:

1. The predicate and proposed devices are intended for the same use.
2. The design of each predicate and proposed device are the same.
3. The component materials used to manufacture each of the rings have not changed except for the addition of the Duraflo® Treatment in the proposed rings.

4. The packaging materials are the same as those used in the currently marketed annuloplasty models (predicate devices).

Note: The term "substantial equivalence" as outlined in this pre-market notification and the supporting information pertaining to equivalence are intended only to demonstrate equivalence to the predicate products for purposes of obtaining clearance of the device pursuant to the Federal Food, Drug and Cosmetic Act. Reference to equivalence as outlined above is in no way related to the term "equivalent" or similar terminology as outlined under the patent laws.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 7 1998

Mr. Larry Wood
Manager, Regulatory Affairs
Baxter Healthcare Corporation
CardioVascular Group
17221 Red Hill Avenue (Irvine)
P.O. Box 11150
Santa Ana, CA 92711-1150

Re: K980487
Heparin-Treated Annuloplasty Ring Model Numbers 4425 (mitral),
4525 (Tricuspid), 4475 (mitral), and 4625 (mitral and
tricuspid)
Regulatory Class: III
Product Code: 74 KRH
Dated: February 6, 1998
Received: February 9, 1998

Dear Mr. Wood:

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. Be advised that any promotional or advertisement materials must be consistent with the labeling in the submission (i.e., bear the bolded statement regarding the lack of long-term clinical effectiveness data).

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 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. 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

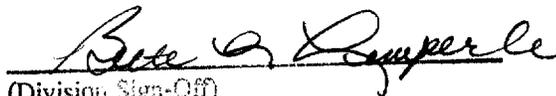
510(k) Number (if known): K980487

Device Name: Baxter Annuloplasty Ring Product Lines (Models 4425, 4525, 4475, and 4625)

Indications For Use: The intended uses of Baxter's Annuloplasty ring products with Duraflo Treatment are intended for use in patients to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines and prevent further dilatation of the annulus.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K980487

(Optional Format 3-10-98)