

K980534

APR 30 1998

SECTION 18: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

18.1 SUBMITTER INFORMATION

- a. Company Name: Medtronic Heart Valves, Inc.
- b. Company Address: 18011 South Mitchell
Irvine, CA. 92714
- c. Company Phone: (714) 474-3943
Company Facsimile: (714) 474-3953
- d. Contact Person: Jean Champion
Manager, Regulatory Affairs
- e. Date Summary Prepared: February 5, 1998

18.2. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: Duran Flexible Annuloplasty Ring and Delivery System
- b. Classification Name: Annuloplasty Ring
21 CFR 870.3800

18.3 IDENTIFICATION OF PREDICATE DEVICE

<u>Company</u>	<u>Device</u>	<u>510(k)-No.</u>	<u>Date Cleared</u>
Medtronic, Inc.	Duran Flexible Annuloplasty Ring and Obturator	K893678	11/27/89

18.4 DEVICE DESCRIPTION

The delivery system for the Duran Flexible Annuloplasty Ring consists of the ring holder, template and handle. The annuloplasty ring is mounted onto a rigid, colored plastic holder via sutures. The ring holder is connected to a rigid clear plastic template. The Duran Annuloplasty Ring and Delivery system is available in 25, 27, 29, 31, 33, and 35 mm sizes. A plastic colored handle is provided as part of the delivery system. The handle contains a wire portion for flexibility during use. The handle is provided to assist in the implantation of the assembly to the surgical site.

18.5 SUBSTANTIAL EQUIVALENCE

The Duran Flexible Annuloplasty Ring and Delivery System is substantially equivalent to the current Duran Flexible Annuloplasty Ring and Obturators in commercial distribution by Medtronic, Inc.

The fundamental technical characteristics are similar to those of the predicate device and are listed on the comparison chart provided in this 510(k) submission. The annuloplasty ring has not changed from the predicate device, and is identical. The intended use of the ring holder and handle has not changed from the predicate device. Similar materials are used in the Duran Flexible Annuloplasty Ring and Delivery System as in the predicate device.

18.6 INTENDED USE

The Duran Flexible Annuloplasty Ring is indicated for the reconstruction and/or remodeling of the pathologic mitral and tricuspid valves.

18.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Duran Flexible Annuloplasty Ring and Delivery System with the predicate device is provided within this submission. Both the Duran Flexible Annuloplasty Ring and Delivery System and the predicate device are composed of an annuloplasty ring, ring holder, template and obturators. A handle can be used with both systems to assist in delivery of the ring to the surgical site. The materials used in the devices are similar and the sizes of the annuloplasty rings have not changed.

18.8 PERFORMANCE DATA

The Duran Flexible Annuloplasty Ring Delivery System is subjected to performance bench testing in accordance with applicable industry and clinical standards. Physical performance studies are conducted to verify that the delivery components perform as intended after routine sterilization, resterilization and accelerated aging cycles. Packaging testing was completed to verify that the packaging configuration was able to provide a double aseptic sterile system and no detrimental effects occurred during routine shipping and handling of the product. Shelf life studies are used to qualify expiration dates of 3 and 5 years.

Complete sterilization validations of the product using a 100% Ethylene Oxide sterilization cycle were found to be acceptable.

Biocompatibility testing of materials in accordance with the "Biological Evaluation of Medical Devices – Part I: Guidance on Selection of Tests," ANSI/AAMI 10993-1, were conducted and found to be acceptable.

18.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.



APR 30 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jean Champion
Senior Regulatory Affairs Manager
Medtronic Cardiac Surgery
Medtronic Heart Valves, Inc.
18011 South Mitchell
Irvine, CA 92714

Re: K980534
Medtronic Duran Flexible Annuloplasty Ring Model #H680H
Regulatory Class: III (Three)
Product Code: KRH
Dated: February 10, 1998
Received: February 11, 1998

Dear Ms. Champion:

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.

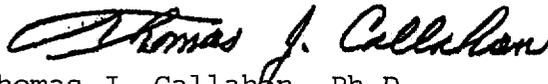
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Jean Champion

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

Enclosure

INDICATION FOR USE

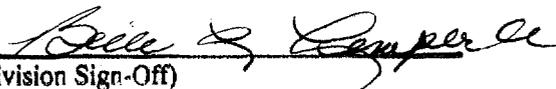
510(k) Number: To Be Assigned By FDA

Device Name: Duran Flexible Annuloplasty Ring Delivery System

Indications For Use: The Duran Flexible Annuloplasty Ring is indicated for the reconstruction and/or remodeling of the pathologic mitral and tricuspid valves. Combined atrioventricular valve insufficiency and stenosis may be corrected by appropriate commissurotomy and valvular remodeling.

(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 K980534

Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109)