K984435

JAN 7 1999

SUMMARY OF SAFETY AND EFFECTIVENESS

MEDTRONIC KHONSARI™ ANNULOPLASTY BAND

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

I SUBMITTER INFORMATION

Company Name:	Medtronic Heart Valves (Medtronic)
Company Address:	7000 Central Avenue N.E. Minneapolis, MN 55432
Company Phone:	(612) 514-2700
Company Facsimile:	(612) 514-2890
Contact Person:	Julie Sherman Product Regulation Manager
Date Summary Prepared:	December 10, 1998

II DEVICE IDENTIFICATION

Trade/Proprietary Name:	Medtronic KHONSARI™ Annuloplasty Band [Model H609M]
21 CFR Reference:	870.3800
21 CFR Common Name:	Ring, Annuloplasty
Class:	Pre-amendment Class III
Panel:	CV (74) KRH

III IDENTIFICATION OF PREDICATE DEVICE

Device	510(k) #
Medtronic SCULPTOR® Annuloplasty Ring [Model 605M]	K905175

The 510(k) also includes references to the following marketed devices:

Medtronic Posterior Annuloplasty Ring [Model 607]	K960356
Cosgrove-Edwards™ Annuloplasty System [Model 4600]	K923367
Medtronic DURAN Annuloplasty Ring [Model H608H]	K980534

IV DEVICE DESCRIPTION

The Medtronic KHONSARI Annuloplasty Band [Model H609M] is an implantable, flexible, adjustable band. The band reduces and stabilizes the mitral valve annulus in patients undergoing mitral valve repair. The body of the band is made of braided polyester and has drawstrings that permit segments of the annulus to be independently shortened.

The band contains a flexible (non-metallic) radiopaque marker that enables radiographic visualization of its entire length. Eight radially spaced surgeon's flags indicate recommended locations for implantation sutures. Each annuloplasty band is attached to a holder. A circumferential groove in the holder protects the drawstrings from entrapment by the implanting sutures. The stem of the handle is malleable to facilitate seating of the band during placement.

The four adjustable drawstrings are coiled within cylindrical canisters on the holder. A retaining suture secures each end of the band to the holder. The drawstrings will automatically release from the holder as it is removed from the band.

V DESCRIPTION OF INTENDED USE

The Medtronic KHONSARI Annuloplasty Band is for use in those patients undergoing surgery of diseased or damaged mitral valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty bands provide support for and restrict dilatation of the posterior mitral valve annulus.

VI SUBSTANTIAL EQUIVALENCE

The Medtronic KHONSARI Annuloplasty Band [Model H609M] is substantially equivalent to the Medtronic SCULPTOR Annuloplasty Ring [Model 605M]. The KHONSARI Annuloplasty Band is manufactured based on modifications to the manufacturing processes of the SCULPTOR Annuloplasty Band. Both devices contain equivalent raw materials and are produced using equivalent manufacturing, packaging and sterilization processes. Both devices are indicated for surgical repair of mitral valves.

The KHONSARI Annuloplasty Band is also equivalent to the Posterior Annuloplasty Band [Model 607] manufactured by Medtronic and the Cosgrove-Edwards™ Annuloplasty System [Model 4600] by virtue of the flexible, open band configuration (no stiffener) of all three devices.

VII TECHNOLOGICAL CHARACTERISTICS

Both the KHONSARI Annuloplasty Band and the SCULPTOR Annuloplasty Ring are manufactured using the same white polyester braided fabric as is used in the predicate device. The radiopaque marker, identification tag and suture used for sewing of the polyester fabric and surgeon markers remains the same. The drawstrings are made from the same raw material. Both products are manufactured using equivalent manufacturing, packaging and sterilization processes. The KHONSARI Annuloplasty Band is manufactured as an open configuration with a completely flexible band, whereas the SCULPTOR Annuloplasty Ring is manufactured as a complete flexible ring with a a rigid anterior portion.

VIII PERFORMANCE DATA

The KHONSARI Annuloplasty Band was subjected to verification and validation studies to demonstrate that the modifications to the predicated device are appropriate and do not affect the intended use or performance of the device.

Manufacturing process validation was performed. The modified manufacturing processes meet all procedure requirements. Physical performance studies were conducted to verify that the device performs as intended after routine sterilization and accelerated aging cycles. Sterilization validation of the device was also completed. Based on the results of the study, the sterility assurance level (SAL) of the sterlization process was qualified at 10^{-6} sterilization level at a minimum sterilization dose of 25kGy. The verification/validation studies demonstrate that the modifications to the manufacturing process are appropriate and do not affect the intended use of the product.

No changes have been made to the manufacturing or sterilization of this device to warrant new or additional biocompatibility testing of the device components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 1999

Ms. Julie Sherman
Product Regulation Manager
Medtronic Cardiac Surgery
7000 Central Avenue, NE
Minneapolis, MN 55432-3576

Re: K984435
Medtronic Khonsari™ Annuloplasty Band [Model H609M]
Regulatory Class: III (Three)
Product Code: KRH
Dated: December 10, 1998
Received: December 11, 1998

Dear Ms. Sherman:

This letter corrects our substantially equivalent letter of January 7, 1999, regarding the incorrect trade name and model number.

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 Good

Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 continue 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 their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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): K98 4 4 3 5

Device Name: Medtronic KHONSARI ™ Annuloplasty Band [Model H609M]

Indications for Use:
For use in those patients undergoing surgery of diseased or damaged mitral valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty bands provide support for and restrict dilatation of the posterior mitral valve annulus.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
Per 21 CFR 801.109

Bette K. Kimpel

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 984435