

K 052 860

NOV 10 2005

SUMMARY OF SAFETY AND EFFECTIVENESS

CG Future® 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: 8299 Central Avenue N.E.
Minneapolis, MN 55432

Company Phone: (763) 514-6600
Company Facsimile: (763) 514-6775

Contact Person: Julie Sherman
Regulatory Affairs Manager

Date Summary Prepared: October 10, 2005

II DEVICE IDENTIFICATION

Trade/Proprietary Name: CG Future® Annuloplasty Band
[Model 638B]

21 CFR Reference: 870.3800

21 CFR Common Name: Ring, Annuloplasty

Classification: Class II

Panel: CV (74) KRH

III IDENTIFICATION OF PREDICATE DEVICE

<u>Device</u>	<u>Model #</u>	<u>FDA Clearance</u>
CG Future® Annuloplasty Band	638B	K011395, July 12, 2001

IV DEVICE DESCRIPTION

The CG FUTURE Band is a single use, permanent, semi-rigid, implantable device intended for the repair of a patient's mitral valve. The CG FUTURE Band consists of a partial band of polyester fabric covering a formed, metallic (MP35N) wire stiffener material with eyelets formed at both ends. The stiffener element is over-molded with LSR silicone. The band is marked at three locations (the two trigone locations and the center) with green-colored suture.

Two trigone markers identify the eyelets in the stiffener to facilitate anchoring of the stiffener into the trigones by the surgeon with sutures. The individual band size (26, 28, 30, 32, 34, 36, and 38mm) represents the widest, straight-line distance as measured at the inside of the fabric-covered band. The band is designed for implantation in the mitral position only.

The CG FUTURE Band is used with associated accessories that include a holder, sizers and a handle. Implantation of the band is aided with the disposable band holder. The band is released from the holder by cutting suture at two points. The CG FUTURE Band sizer set is used to assess appropriate band size. The sizers cover all seven sizes of the CG FUTURE Band and are marked with the band size and the trigone locations. The sizers are reusable and are provided non-sterile. The reuseable annuloplasty handle, which is available in two lengths, interfaces with both the holder and the sizers.

V DESCRIPTION OF INTENDED USE

The CG Future® Annuloplasty Band is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling.

VI SUBSTANTIAL EQUIVALENCE

The CG FUTURE Band and the modified CG FUTURE Band are manufactured using the same raw materials, manufacturing, packaging and sterilization processes. Both products have the same indications for use.

VII PERFORMANCE DATA

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

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 2005

Medtronic Cardiac Surgery
c/o Ms. Julie Sherman
Regulatory Affairs Manager
8299 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K052860
CG Future® Annuloplasty Band
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II (Two)
Product Code: KRH
Dated: October 10, 2005
Received: October 11, 2005

Dear Ms. Sherman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K05 2 8 6 0

Device Name: CG Future® Annuloplasty Band [Model 638B]

Indications for Use:

The CG Future® Annuloplasty Band is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Dr. Anne R. Kochner
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K052860