K061127

MAY 23 2006

510(k) Summary – CG Future® Annuloplasty Ring

Applicant (Sponsor) Name and Address

Medtronic Heart Valves (Medtronic)

8299 Central Avenue N.E. – M.S. 108

Minneapolis, MN 55432

Establishment Reg. No.: 2127690

Contact Name and Phone

Phil Neururer

Regulatory Affairs Specialist

Company Phone: (763) 514-6600

Company Fax: (763) 514-6775

Device Trade/Proprietary Name

CG Future® Annuloplasty Ring (CG Ring)

Device Classification/Common Name/Panel

21 CFR Reference: 870.3800

21 CFR Common Name: Ring, Annuloplasty

Classification: Class II

Panel: CV (74) KRH

Identification of Predicate Device

Medtronic believes the CG Ring is substantially equivalent to the CG Future® Annuloplasty Band (CG Band) previously cleared to market in the U.S. by FDA on November 10, 2005 (K052860) and also the Duran AnCore® Ring and Band (Duran Product Family) previously cleared to market in the U.S. by FDA on December 5, 2003 (K032810) and may market our device under these equivalencies.

Substantial Equivalence

The CG Ring has the same fundamental scientific technology and intended use as the predicate devices.

Description of Intended Use

The CG Ring 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.

Device Description

The Model 638R CG Ring is based on the marketed released Model 638B CG Band and Model 620R/620B Duran Product Family. The CG Ring is a semi-rigid annuloplasty ring intended for remodeling and/or reconstruction of pathological mitral valves. Similar to the CG Band, the CG Ring is composed of a C-shaped metal stiffener that is covered with silicone and fabric. Unlike the CG Future Band but similar to the Duran Product Family, the CG Ring is a fully closed ring, formed by joining the ends of the stiffener with suture and fabric, resulting in a D-shaped device. In addition, a similar radiopaque strip that is used in the Duran Product Family is placed between the stiffener ends for identification of the device on X-ray.

The disposable CG Ring Holder provides for attachment of the ring, guides the implantation of the ring, and interfaces with the Model 7615 Annuloplasty Handle. There are eight (8) sizes for the holder (24, 26, 28, 30, 32, 34, 36, and 38 mm), and a single holder is provided with each packaged ring assembly. The CG Ring packaging consists of double-aseptic pouches (containing the ring attached to its holder). The pouch assembly is placed in a shelf carton box along with instructions for use and product traceability labels for shipping.

Performance Data

The CG Ring 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2006

Mr. Phil Neururer
Regulatory Affairs Specialist
Medtronic, Incorporated
8299 Central Avenue N.E.
Minneapolis, MN 55432

Re: K061127
Trade/Device Name: CG Future® Annuloplasty Ring (CG Ring)
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: April 21, 2006
Received: April 24, 2006

Dear Mr. Neururer:

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.

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): K06 1 1 2 7

Device Name: CG Future® Annuloplasty Ring and Band

Indications for Use:

The CG Future® Annuloplasty Ring and 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 ✓ OR Over-The-Counter Use _____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061127