AUG - 7 2010

5. 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CRF 807.92.

I. SUBMITTER INFORMATION

Company Name:	Medtronic CardioVascular – Structural Heart (Medtronic)
Company Address:	8200 Coral Sea Street N.E. Mounds View, MN 55112
Company Phone:	763-514-9840
Company Facsimile:	763-367-8147
Contact Person:	Becky Hannack Senior Regulatory Affairs Specialist
Date Summary Prepared:	April 29, 2010

II. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Contour 3D™ Annuloplasty Ring, Model 690R
21 CFR Reference:	870.3800
21 CFR Common Name:	Ring, Annuloplasty
Classification:	Class II
Panel:	CV (74) KRH

III. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:	MC^3 Tricuspid Annuloplasty System
510(k) Number:	K020864
510(k) Clearance Date:	April 17, 2002

IV. DEVICE DESCRIPTION

The Contour 3D™ Annuloplasty Ring, Model 690R, consists of a titanium core encapsulated with silicone and covered with polyester fabric. The titanium core enables radiographic visualization of the device.

The Contour 3D™ Ring is for single-use only. It is available in six sizes for the tricuspid position: 26, 28, 30, 32, 34, and 36 mm. The device size is identified by the inside diameter of the ring at its widest point. The ring is marked at three (3) points by colored sutures. The three (3) markers correspond to the commissures of the tricuspid valve. The ring is packaged with a single annuloplasty ring assembled on a disposable holder.

V. DESCRIPTION OF INTENDED USE

The Contour 3D™ Annuloplasty Ring is indicated for the reconstruction and/or remodeling of pathological tricuspid valves.

VI. SUBSTANTIAL EQUIVALENCE

The Contour 3D™ Annuloplasty Ring is substantially equivalent to the predicate device, the MC^3 Tricuspid Annuloplasty System. Both devices are indicated for and intended to be used with tricuspid annuloplasty procedures for reconstructive treatment of valvular insufficiency. The two devices have the same technological characteristics as they are both rigid remodeling rings designed for use in the tricuspid valve. They both consist of a titanium core encapsulated with silicone and covered with polyester fabric. Both rings are provided sterile, mounted on a holder, and come in varying sizes. Substantial equivalence has also been determined by comparing results of tensile strength and suture pull-out performance testing of the two devices.

VII. PERFORMANCE DATA

The Contour 3D™ Annuloplasty Ring was subjected to verification and validation studies. This testing was conducted in accordance with the FDA Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and Staff issued January 31, 2001. The results of the testing demonstrate the Contour 3D™ Ring is safe and effective for its use in the reconstruction and/or remodeling of pathological tricuspid valves.

Testing included: biocompatibility, computational structural analysis, tensile strength, suture pull out, fatigue, MRI, radiopacity, sterilization validation, bioburden, pyrogen, and shelf life validation.

The following page contains a table of the standards applicable to this device.

Standard Number	Standard Title
EN ISO 13485:2003	Medical devices – Quality management systems – requirements for regulatory purposes
EN ISO 14971:2007	Application of risk management to medical devices
EN ISO 10993-1:2003	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 11607-1:2006	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 17665-1:2006	Sterilization of health care products Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN 556-1:2001	Sterilization of Medical Devices – Requirements for medical devices to be designated "sterile" – Part 1: Requirements for terminally sterilized medical devices
EN 980:2008	Graphical symbols for use in the labeling of medical devices
EN 1041:1998	Information supplied by the manufacturer with medical devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG - 7 2010

Medtronic Inc
c/o Ms. Becky Hannack
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE
MoundsView, MN 55112

Re: K101212
Medtronic Contour 3D Annuloplasty Ring
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II (two)
Product Code: KRH
Dated: July 29, 2010
Received: July 30, 2010

Dear Ms. Hannack:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

K101212

AUG - 7 2010

510(k) Number (if known): K101212

Device Name: Medtronic Contour™ 3D Annuloplasty Ring

Indications For Use:

The Contour 3D™ Ring is indicated for the reconstruction and/or remodeling of pathological tricuspid valves.

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 Devices
510(k) Number K101212