K033685

AUG - 3 2004

Section II

Summary of Safety and Effectiveness (as required by 21 CFR 807.92)

Northrup Universal Annuloplasty System™

Submitter: MedicalCV, Inc.
9725 South Robert Trail
Inver Grove Heights, MN 55077
USA

Contact: Denny Steger
V.P. RA/QA
Phone: 651 452 3000
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Date of Summary: October 15, 2003

Classification Name: Annuloplasty Ring

Common Name: Annuloplasty Ring

Proprietary Northrup Universal Annuloplasty System™

Description of Device: The Northrup Universal Annuloplasty System consists of an annuloplasty ring mounted on a holder assembly for implantation in the mitral or tricuspid position. A complete set of instrumentation is available separately to properly size the annulus.

Statement of Intended Use: The MedicalCV Northrup Universal Annuloplasty System is indicated as reinforcement for repair of the human cardiac mitral and tricuspid valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

Technological Comparison: The Northrup Universal Annuloplasty System is a flexible annuloplasty ring that can be implanted either as a partial or complete ring, according to the surgeon's preference and/or patient condition. For purposes of this submission, the Northrup Universal Annuloplasty System was compared to the following predicate device(s):

- CarboMedics AnnuloFlex Annuloplasty System - K992056
  - can be implanted either as a partial or complete ring with identical function as the Northrup Universal Annuloplasty System
- Edwards Lifesciences Cosgrove-Edwards Annuloplasty System – K923367
- Baxter Carpentier-Edwards Physio Annuloplasty Ring – K926138

Testing: The results of biocompatibility testing support that the materials used in the manufacture of the Northrup Universal Annuloplasty System are non-toxic, non-hemolytic, and non-pyrogenic. All testing was conducted under Good Laboratory Practices per 21 CFR Part 58. Mechanical Integrity testing for the Northrup Universal Annuloplasty System includes suture retention testing which demonstrated that the design provided for a more than adequate retention force as compared to the predicate device. Testing demonstrated that the Northrup Universal Annuloplasty System is substantially equivalent to the predicate device for repair of the mitrial or tricuspid valve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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MedicalCV, Inc.
c/o Mr. Denny Steger
Vice President Regulatory Affairs
9725 South Robert Trial
Inver Grove Heights, MN 55077

Re: K033685
Northrup Universal Annuloplasty System™
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II (two)
Product Code: KRH
Dated: June 22, 2004
Received: June 24, 2004

Dear Mr. Steger:

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 (301) 594-4646. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Donna R. Vechinski

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

Enclosure

Indications for Use Statement

510(K) Number: K033685

Device Name: Northrup Universal Annuloplasty System™

Indications for Use: The MedicalCV, Inc. Northrup Universal Annuloplasty System is indicated as a reinforcement for repair of the human cardiac mitral or tricuspid valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

Prescription Use__X__ OR Over–the-Counter Use____
(Per 21 CFR 801.109)

(Please do not write below this line – Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K033685