

1023880

ATTACHMENT V

DEC 11 2002

510(k) SUMMARY

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**Statement** Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "... 510(k) Summaries and 510(k) Statements ..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

**MODIFIED DEVICE NAME:** CardioVations Steerable  
Coronary Sinus Catheter

**PREDICATE DEVICE NAME:** Endocoronary Sinus Catheter

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**Device Description** The Steerable Coronary sinus Catheter is a 9 Fr., three-lumen catheter in the distal balloon. The three lumen are used to inflate the balloon (to occlude the coronary sinus), monitor coronary sinus pressure and for delivery of cardioplegia solution.

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**Intended Use** The catheter is designed to occlude the coronary sinus, deliver cardioplegic solution to the coronary sinus and monitor the coronary sinus pressure during cardiopulmonary bypass.

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**Indications Statement** The Steerable Coronary Sinus Catheter is indicated for occlusion of the coronary sinus, delivery of cardioplegic solution, and monitoring of coronary sinus pressure during cardiopulmonary bypass.

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**Technological Characteristics** The modified device has the same technological characteristics as the predicate device. The form, fit, function and method of operation are similar.

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510(k) SUMMARY (continued)

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Performance Data                      Results of verification testing indicates that the product meets the established performance requirements.

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Conclusion                                Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

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Contact                                     Peter Cecchini  
    Manager  
    Regulatory Affairs  
    ETHICON, Inc.  
    Rt. 22 West  
    Somerville, NJ 08876-0151

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Date    November 20, 2002



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 11 2002

Ethicon, Inc.  
c/o Mr. Peter Cecchini  
Route 22 West  
Somerville, NJ 08876

Re: K023880  
CardioVations Steerable Coronary Sinus Catheter  
Regulation Number: 870.4210  
Regulation Name: CPB Catheter, Cannula, Tubing  
Regulatory Class: Class II (two)  
Product Code: DWF  
Dated: November 20, 2002  
Received: November 21, 2002

Dear Mr. Cecchini:

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

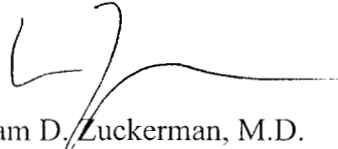
Page 2 – Mr. Peter Cecchini

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). 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,



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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): \_\_\_\_\_

Device Name: CardioVations Steerable Coronary Sinus Catheter

Indications for Use: The Steerable Coronary Sinus Catheter is indicated for occlusion of the coronary sinus, delivery of cardioplegic solution, and monitoring of coronary sinus pressure during cardiopulmonary bypass.

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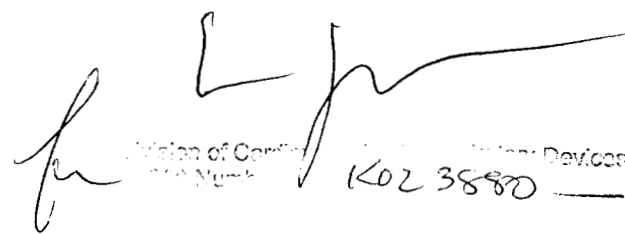
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The Counter Use

  
Division of Cardiovascular Devices  
K023880

(Optional Format 1-2-9G)

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CardioVations Steerable Coronary Sinus Catheter  
ETHICON, Inc.