OCT 6 - 2004

K 042156

510(k) SUMMARY

510(k) number: _____

This summary of information is being provided in accordance with 21 CFR 807.92(a).

Applicant Information:	Cardeon Corporation 10600 N. Tantau Avenue Cupertino, CA 95014
Contact Person:	Jane Beggs Regulatory Affairs Cardeon Corporation
Date:	9 August 2004
Device Trade Name:	Cobra™ Catheter
Device Common Name	Catheter, cannula and tubing, vascular, cardiopulmonary
Regulation No.:	bypass 870.4210
Classification / Code:	Class II / DWF

Indications for Use: The Cardeon Cobra Catheter is indicated for use in open chest surgery on cardiopulmonary bypass up to 6 hours. It is used to cannulate the aorta and provide hypothermic arch perfusate and normothermic corporeal perfusate.

Summary of Substantial Equivalence: The Cobra Catheter is substantially equivalent to currently marketed devices used to directly cannulate the aorta and return perfusion to patients undergoing general cardiac surgery. Perfusion is achieved through standard connections to the extracorporeal circuit.). Intended use and indications for the subject and predicate devices are substantially equivalent for arterial return during CPB. Substantial equivalence is also supported through comparison with several marketed devices with the same indications for use, including arterial return cannulae with directed flow (i.e., specified flow patterns). Directed flow is a feature offered by devices cleared through premarket notification and currently marketed for CPB and peripheral vascular thrombectomy. Selective perfusion systems have been reported on extensively and safely used for over two decades. These selective perfusion systems utilize predicate cannulae and standard perfusion circuitry for cooling the brain independently from the rest of the body. Arterial line pressures, nasopharyngeal and rectal temperatures, radial arterial pressures, oxygen saturation, etc. are standard clinical practices for monitoring the patient used in predicate selective perfusion systems. Technological characteristics (design and materials) of the Cobra Catheter are substantially equivalent to arterial return devices currently marketed for CPB. Differences between the Cobra Catheter and currently marketed devices do not substantially alter arterial return during cardiopulmonary bypass.

Product Testing: Substantial equivalence with regard to safety and effectiveness has also been demonstrated through standardized in vitro and in vivo tests as well clinical study.

The Cobra Catheter is an externally communicating device in limited contact with circulating blood. Tests were conducted and inspected in accordance with Good Laboratory Practice Regulation, 21 CFR Part 58. Based on the test results, the Cobra Catheter is biologically compatible, non-toxic and safe for use in limited contact (up to 6 hours) with circulating blood.

In vitro and in vivo testing was designed to ensure device structural integrity, key device functionality and ease of use. Device in vivo performance was evaluated using standard surgical techniques and practices for cardiopulmonary bypass and patient monitoring. Test results provided a high degree of confidence that the Cobra Catheter function as intended. Many of the tests allowed direct comparison to currently marketed devices.

Clinical studies were conducted to demonstrate the safety and effectiveness of the Cobra Catheter. Feasibility and randomized clinical studies demonstrated that adequate venous oxygen saturation was delivered with differential temperatures indicating the preservation of cerebral autoregulation. Thus, the Cobra Catheter is substantially equivalent to predicate arterial return devices with regard to intended use, technological characteristics and device performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2004

Cardeon Corp.
c/o Ms. Jane Beggs
Regulatory Affairs
10600 N. Tantau Avenue
Cupertino, CA 95014

Re: K042156
Cardeon® Cobra™ Catheter
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Catheter, Cannula, or Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: August 9, 2004
Received: August 10, 2004

Dear Ms. Beggs;

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,

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): _____

Device Name: Cardeon® Cobra™ Catheter

Indications for Use:

The Cardeon Cobra Catheter is indicated for use in open chest surgery on cardiopulmonary bypass up to 6 hours. It is used to provide separated perfusion of the arch and distal thoracic aorta with temperature differential, if desired.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the Counter Use _____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042156