K03023 /

APR 1 8 2003

Summary of Safety and Effectiveness

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Vitalcor's, Inc. devices are substantially equivalent to the cited predicate device based in fact that both devices have the same stated intended use, have very similar technologic characteristics, including material, dimensional specifications and performance characteristics.

COMPANY AND CONTACT PERSON

Vitalcor, Inc.
100 E. Chestnut Avenue
Westmont, Illinois 60559
William Huck
President

DEVICE NAME

Coronary Artery Perfusion Cannula with Self-Inflating Balloon

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

The claim of substantial equivalence is based upon the following device:

- California Medical Laboratories, Inc. Aortic Root Cannula

DESCRIPTION OF DEVICE

The Coronary Artery Perfusion Cannula with Self-Inflating Balloon consists of a single lumen vinyl tube provided for with a vinyl female luer connector bonded proximally and a vinyl cuff bonded distally. The cuff is pre-molded to its inflated configuration and is purposely positioned directly over a hole generated in the extruded tubing for purposes of receiving the infused cardioplegia solution. The subject device is provided for in five sizes based upon the diameter of the cuff consisting of 4, 5, 6, 7 & 8 mm in diameter. Furthermore, the cannula is pre-shaped into two configurations both straight and right angle.

STATEMENT OF INTENDED USE

The Coronary Artery Perfusion Cannula with Self-Inflating Balloon is indicated for use in delivery of cardioplegia solution directly to the coronary arteries during cardiopulmonary bypass surgery.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

California Medical Laboratories is indicated for use in delivery of cardioplegia solution during cardiopulmonary bypass surgery.

STATEMENT OF COMPARISON OF TECHNOLOGIC CHARACTERISTICS BETWEEN DEVICE AND PREDICATE DEVICE

Vitalcor's, Inc devices have technologic characteristics including material, dimensional and performance characteristics, which are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2003

Vitalcor, Inc.
c/o William C. Huck
President
100 East Chestnut Avenue
Westmont, IL 60559

Re: K030231
Trade/Device Name: Coronary Artery Perfusion Cannula with Self-Inflating Balloon
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: January 17, 2003
Received: January 22, 2003

Dear Mr. Huck:

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 Cardiovascualr Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030231

Device Name: Coronary Artery Perfusion Cannula with Self-Inflating Balloon

Indications For Use: The Coronary Artery Perfusion Cannula with Self-Inflating Balloon is indicated for use in delivery of cardioplegia solution directly to the coronary arteries during cardiopulmonary bypass surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030231

Prescription Use X **OR** **Over-The-Counter Use** _____ **Per 21 CFR 801.109**