

JUN 26 1998

K973298

Summary of Safety and Effectiveness

Trade Name:

Cardima Vueport™ Coronary Sinus Balloon Occlusion Guiding Catheter

Manufacturer:

Cardima, Inc.
47266 Benicia Street
Fremont, CA 94538-7330
Contact: Shelley Trimm
Establishment Registration Number: 29-51-009

Classification Name:

Catheter Cardiovascular Balloon Type (21 CFR 870.1240)

Device Classification:

Class II (21 CFR 870.1240) Panel: Circulatory System Devices Panel, DCRND

Intended Use and Product Description:

The Cardima Vueport™ *Coronary Sinus Balloon Occlusion Guiding Catheter* is intended for temporary occlusion of the coronary sinus ostium during a venogram and to serve as a conduit for other introduction of devices to the coronary venous system.

The Cardima Vueport™ is a sterile, single use only, dual lumen, balloon tipped guiding catheter with various tip configurations. The Cardima Vueport™ has a "Y" connector at the proximal end and each branch of the "Y" houses a lumen. The smaller lumen extends from a one-way stopcock to the balloon and is used for air delivery and withdrawal. By using the vented 3 cc syringe (included with the Vueport), to inflate the balloon, the coronary sinus ostium can be temporarily occluded to perform a coronary venogram. The larger lumen extends from a female luer to the open atraumatic catheter tip. The larger lumen is a guide to the coronary sinus vasculature for injecting contrast media and as a conduit for other medical devices.

Sterilization, Packaging and Pyrogenicity:

Vueport is individually packaged in a Paperboard-SBS polyethylene coated (in-side only) tray and inserted into a standard Tyvek/PET-polyethylene pouch. The pouch is heat-sealed to provide a microbial barrier, and is then gamma sterilized. Cardima is using Method 3 of the AAMI "Guideline for Gamma Radiation Sterilization" (1991).

Cardima is using Method 3 of the AAMI "Guideline for Gamma Radiation Sterilization" (1991). The Vueport™ design does not introduce any new or unique challenges to the current validated sterilization process. Given these considerations re-validating the sterilization process used for Vueport was deemed unnecessary.

Substantial Equivalence:

Cardima Vueport™ Coronary Sinus Balloon Occlusion Guiding Catheter is substantially equivalent to Electro-Catheter Corp., Elecath Occlusion Catheter. The Vueport™ also shares similar characteristics with the Zeppelin Balloon Guiding Catheter (K945963, cleared 2/8/95 under the name: The Omniguide Guiding Catheter with Balloon). Establishment of equivalence is based on similarities of intended use, design, and physical characteristics as evaluated by physical bench testing, biocompatibility and animal studies.

Summary of Safety and Effectiveness:

Safety and effectiveness were evaluated through biocompatibility testing, reliability testing and animal studies. Reliability and mechanical testing was conducted on sterilized Vueport™ Coronary Sinus Balloon Occlusion Guiding Catheter with guidance in part from "Electrode Recording Catheter Preliminary Guidance, March 1995". The tests were used to assess the mechanical properties of the catheter and found to be acceptable for the stated intended use.

Animal studies were conducted to evaluate the ability of Vueport™ balloon guiding catheter to occlude the coronary sinus ostium during a venogram. The Vueport™ performance was satisfactory when placed into the coronary sinus ostium, the balloon inflated and deflated and performed acceptable venographs. Cardima Vueport™ Coronary Sinus Balloon Occlusion Guiding Catheter when compared to the control catheter (i.e., Elecath) the performance was equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 1998

Ms. Shelley Trimm
Cardima, Inc.
47266 Benicia Street
P.O. Box 14172
Fremont, CA 94538-7330

Re: K973298
VUEPORT Coronary Sinus Balloon Occlusion Guiding Catheter
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: June 5, 1998
Received: June 8, 1998

Dear Ms. Trimm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Shelley Trimm

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973298

Device Name: VUEPORT CORONARY SINUS
Balloon Occlusion Guiding Catheter

Indications For Use:

The VUEPORT is intended for use to access the coronary sinus and perform occlusive venograms. The catheter may serve as a conduit for the delivery and support of other devices.

Tara A. Ryan

(Division Sign Off)
Division of Cardiovascular
and Neurological Devices

510(k) Number K973298

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)