

K980128

JUL 24 1998

510(k) SUMMARY

A. Name and Address

Cardio Medical Solutions, Inc.
17080 Newhope Street
Fountain Valley, CA. 92708

B. Telephone and Fax Number of Contact

Phone: (714) 427 - 6350
Fax: (714) 427 - 6354

C. Contact Person

Anthony Nobles
Chief Scientific Officer &
Vice President, R&D

D. Date of Summary Preparation

January 9, 1998

E. Name of the Device

1. Trade or Proprietary

Baladi Inverter™ with Coaxial Aortic Punch

2. Common or Usual

Vascular Clamp and Aortic Punch

3. Classification Name

Vascular Clamp and Aortic Punch

F. Description of the Device

The Baladi Inverter™ with Coaxial Aortic Punch is used to create hemostasis and punch a hole in the aorta to facilitate the anastomosis during coronary arterial bypass grafting (CABG) procedures.

G. Summary of Substantial Equivalence

The predicate devices are standard:

Vascular clamps for total and partial occlusion. These devices are distributed by various manufacturers in various sizes and configurations.

Aortic punches for punching holes in the aorta facilitating the completion of the anastomosis during CABG procedures. These devices are distributed by Medtronic, Davis + Geck, and various other manufacturers in various sizes.

The Baladi Inverter™ with Coaxial Aortic Punch provides partial occlusion and punches a hole in the aorta facilitating the completion of the anastomosis during CABG procedures.

H. Predicate Devices

Debakey Vascular Clamp
Cooley Vascular Clamp
Medtronic Punch
Hancock Aortic Punch (K800122)
Davis + Geck CardioPunch

I. Summary of Non-Clinical Testing

The Baladi Inverter™ with Coaxial Aortic Punch has undergone all of the following tests:

Sterilization Qualification
Biocompatibility
Design Verification

J. Summary of Clinical Testing

The Baladi Inverter™ with Coaxial Aortic Punch has undergone the following studies:

An Animal Clinical Study of device effectiveness concluded that the device had no adverse effects. The Baladi inverter™ successfully maintained hemostasis and successfully punched the aorta facilitating the anastomosis and completion of the CABG procedure. Histopathology results revealed no device-related issues.

A Cadaver Study was performed and the study supports the conclusion that the Baladi Inverter™ with Coaxial Aortic Punch does not represent any new issues of Safety or Efficacy.

Human Clinical Studies were performed and the device performed clinically as expected. There were no complications or adverse events reported. The device is considered safe and effective when used according to the device labeling.

K. HAZARD ANALYSIS

The data supports the conclusion that the Baladi Inverter™ with Coaxial Aortic Punch has a Very Low (VL) rating and presents no new issues of safety during the CABG procedure.

L. CONCLUSION

The sponsor believes that the data submitted for the Baladi Inverter™ with Coaxial Aortic Punch constitutes valid scientific evidence. The expected results with respect to procedural success and complications are well defined.

The sponsor believes that the Baladi Inverter™ is safe and effective when used for CABG procedures according to the device labeling.

The sponsor believes that the Baladi Inverter™ with Coaxial Aortic Punch presents no new issues of safety or efficacy during the CABG procedure.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 1998

Mr. Thomas P. Schroeder
VP, Regulatory Affairs & Quality Assurance
Cardio Medical Solutions, Inc.
17080 Newhope Street
Fountain Valley, CA 92708

Re: K980128
Trade Name: Baladi Inverter™ with Attached Aortic Punch
Regulatory Class: II
Product Code: DXC
Dated: July 17, 1998
Received: July 20, 1998

Dear Mr. Schroeder:

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.

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) 594-4618. 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 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): K980128

Device Name: Baladi Inverter™ with Attached Aortic Punch

Indications For Use:

The Baladi Inverter™ with Coaxial Aortic Punch is intended for use by cardiac surgeons during Coronary Artery Bypass Grafting procedures to maintain hemostasis and punch a hole in the aorta to facilitate the completion of the proximal anastomosis.



(Division Sign Off)
Division of Neurological Devices
 510(k) Number K980128

(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

(Optional Format 1-2-96)