**510(k) SUMMARY**
**Cardiva Medical, Inc.**
**Boomerang™ Wire**
**510(k) Notification**

SEP - 1 2006

## GENERAL INFORMATION

**Manufacturer:** Cardiva Medical, Inc.
2585 Leghorn Street
Mountain View, CA 94043
Phone: (650) 964-8900
Facsimile: (650) 964-8911
Establishment Registration Number: 3004182619

**Contact Person:** Glenn Foy
President

**Date Prepared:** 4/14/2006

## DEVICE INFORMATION

**Trade name:** Boomerang™ Wire

**Classification Names:** Vascular Clamp (21 C.F.R. § 870.4450);
Catheter, Intravascular, Diagnostic (21 C.F.R. § 870.1200);
Surgical Vessel Dilator (21 C.F.R. § 870.4475);
Blood Access Device and Accessories (21 C.F.R. § 870.5540)

**Classification:** Class II

## PREDICATE DEVICES

Cardiva Medical VasoStasis Vascular Closure System (K041486)
Radi Medical Systems AB, FemoStop™ System (K915280)
CardioThoracic Systems, Inc., CTS FloCoil™ Shunt (K970638)

## INTENDED USE/INDICATIONS FOR USE

The Cardiva Medical Boomerang™ Wire is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression. The Boomerang™ Wire is indicated for use in patients undergoing diagnostic femoral artery catheterization procedures, using 5 or 6 Fr introducer sheaths.

## DEVICE DESCRIPTION

The Boomerang™ Wire consists of a sterile disposable Boomerang Wire and a sterile disposable Boomerang Clip (refer to the detailed Figures 1,2,3 in Section VIII). In conjunction with manual compression, the Boomerang Wire provides hemostasis at a femoral access site after femoral arterial catheterization while allowing continued distal perfusion. After completion of catheterization, the Boomerang Wire is inserted into the artery through the existing introducer sheath. After insertion, the distal tip of the Boomerang Wire is deployed, which opens the flat, low-profile Boomerang Disc within the lumen of the femoral artery. The Boomerang Disc is then pulled back gently to the distal end of the introducer sheath. The introducer sheath is then removed from the vessel over the Boomerang Wire and the low-profile Boomerang Disc is positioned against the inside of the arteriotomy. Gentle upward tension is applied to the Boomerang Wire, which conforms the Boomerang Disc to the contours of the vessel and secures it against the intima, sealing the arteriotomy. The tension is then held in place by the external Boomerang Clip at the surface of the skin at the puncture site. The tension between the Boomerang Disc and the Boomerang Clip creates a site-specific compression of the arteriotomy and tract and establishes temporary hemostasis. This allows natural recoil of the smooth muscle of the vessel wall to occur at the arteriotomy site while the body's natural clotting process begins. Following the procedure, the Boomerang Disc is collapsed and the Boomerang Wire is completely removed from the artery. No part of the device is left behind nor is there any material introduced to alter the body's own natural clotting process. Final closure of the vessel occurs with manual compression to close the remaining needle puncture site left by removing the Boomerang Wire.

## SUBSTANTIAL EQUIVALENCE

The Boomerang Wire is substantially equivalent to predicate devices currently being marketed. The marketed predicates are identified above. The Boomerang Wire is substantially equivalent to the predicate devices with regard to function, intended use, physical characteristics, materials and performance testing.

All necessary testing was performed on the Boomerang Wire to ensure the product is substantially equivalent to the predicates and that any differences do not have a significant effect on safety and effectiveness.

## PERFORMANCE TESTING

Various testing which included bench, biocompatibility, and animal testing was performed on the Boomerang Wire to ensure the product and the product materials were adequately tested and evaluated to demonstrate the product meets or exceeds the performance requirements and is safe and effective for its intended use. In addition, post market clinical data have been included to further support that the product meets or exceeds the performance requirements and is safe and effective for its intended use.

## CONCLUSION

The Boomerang Wire was properly designed, tested and shown to be substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 2006

Cardiva Medical, Inc.
c/o Mr. Michael J. Billig
Regulatory Consultant
Experien Group, LLC
155 Moffett Park Drive, Suite A-101
Sunnyvale, California 94089

Re: K061075
Cardiva Medical Boomerang™ Wire System, Models 56 and 610
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: August 1, 2006
Received: August 3, 2006

Dear Mr. Billig:

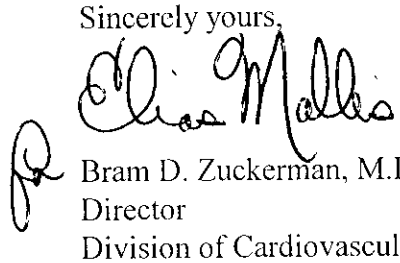
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

## Indications for Use

510(k) Number (if known): K061075

Device Name: Cardiva Medical Boomerang™ Wire

Indications For Use:

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Prescription Use _X_ (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061075