

SECTION 6
510(k) SUMMARY

510(k) Notification K082930

GENERAL INFORMATION

Applicant:

Cardiva Medical, Inc.
2585 Leghorn Street
Mountain View, CA 94043
Phone: 650-964-8900
Facsimile: 650-964-8911

FEB 13 2009

Contact Person:

Kit Cariquitan
Regulatory Consultant
Experien Group, LLC
Phone: 408-400-0856
Facsimile: 408-400-0865
Email: kitc@experiengroup.com

Date Prepared: September 30, 2008

Classification:

21 CFR §870.4450, Class II

Product Code:

DXC

Trade Name:

Cardiva Catalyst™ III System

Generic/Common Name:

Vascular Clamp

PREDICATE DEVICE

Cardiva Medical Boomerang™ Catalyst II System (K072297)

INTENDED USE

The Cardiva Catalyst™ III System with Protamine Sulfate is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression in heparinized patients. The Cardiva Catalyst™ III System is indicated for use in patients undergoing diagnostic and/or interventional femoral artery catheterization procedures using 5F, 6F or 7F introducer sheaths.

SECTION 6
510(k) SUMMARY (CONT.)

PRODUCT DESCRIPTION

The Cardiva Catalyst™ III System is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression. The Cardiva Catalyst III system includes a design modification which involves the addition of Protamine Sulfate to the existing Boomerang Catalyst II System coating to further minimize ooze from the tissue tract and promote the hemostasis process in heparinized patients. The Cardiva Catalyst III System maintains the same indication for use as the Boomerang Catalyst System family of devices.

The Cardiva Catalyst III System consists of a sterile disposable Cardiva Catalyst III wire and a sterile disposable Catalyst Clip. The Cardiva Catalyst III System is specifically designed for use with heparinized patients. In conjunction with manual compression, the Cardiva Catalyst III System provides temporary hemostasis at a femoral access site after femoral arterial catheterization while allowing continued distal perfusion. After completion of catheterization, the Cardiva Catalyst III wire is inserted into the artery through the existing introducer sheath. After insertion, the distal tip of the Cardiva Catalyst III wire is deployed, which opens the flat, low-profile Catalyst Disc within the lumen of the femoral artery. During dwell, natural recoil of the smooth muscle of the vessel wall occurs at the arteriotomy site. A biocompatible coating on the Cardiva Catalyst III Wire aides the body's natural hemostatic process and promotes ease of removal. Specifically, the Cardiva Catalyst III System's biocompatible coating includes a minimal amount of Protamine Sulfate to further aid the body's natural hemostatic process in heparinized patients. Following the procedure, the Catalyst Disc is collapsed and the Cardiva Catalyst III wire is completely removed from the artery. No part of the device is left behind. Final closure of the arteriotomy occurs by applying gentle manual or mechanical compression after removal of the Cardiva Catalyst III System.

SUBSTANTIAL EQUIVALENCE

The Cardiva Catalyst III System is substantially equivalent to the predicate device with regard to function, intended use, and physical characteristics. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the Cardiva Catalyst III System is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the Cardiva Catalyst III System to support a determination of substantial equivalence to the predicate device.

SUMMARY

The Cardiva Catalyst III System is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Experien Group LLC
c/o Mr. Kit Cariquitan
Regulatory Consultant for Cardiva Medical
155 Moffett Park Drive, Suite A-2IO
Sunnyvale, CA 94089

Re: K082930
Cardiva Catalyst™ III System with Protamine Sulfate
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: January 21, 2009
Received: January 22, 2009

Dear Mr. Cariquitan:

This letter corrects our substantially equivalent letter of April 23, 2009.

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 (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 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

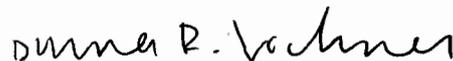
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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

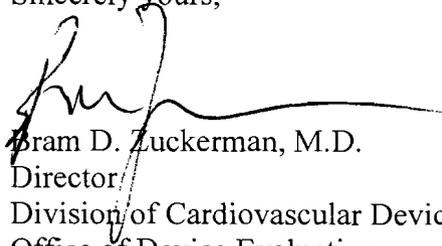


 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal flourish extending to the right.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health