Section 8. Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K130124

MAR 1 4 2013

Applicant Information:

Date Prepared:	January 16, 2013
Name:	Cardiva Medical, Inc. Establishment Registration #3004182619
Address:	888 W. Maude Avenue Sunnyvale, CA 94085

Contact Person:

Name	Michael A Daniel, Acting VP Regulatory Affairs
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Phone Number:	(415) 407-0223
Office:	(925) 254-5228
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Device Information:

Device Trade Name:	Catalyst™ II and III
Common Name:	Vascular Clamp
Classification Name(s):	Vascular Clamp
Product Code/ Regulation:	DXC / (21 CFR §870.4450)
Classification:	Class II

Predicate Device:

Catalyst™ II and III K082930, K072297, and K070485

Device Description:

The Cardiva Catalyst systems are intended to promote hemostasis at arteriotomy sites as adjuncts to manual compression and retain the same indication for use as the Boomerang Catalyst System family of devices. The Cardiva Catalyst systems consist of a sterile disposable Cardiva Catalyst 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 systems provide temporary hemostasis at a femoral access site after femoral arterial catheterization while allowing continued distal perfusion. After completion of catheterization, the Cardiva Catalyst wire is inserted into the artery through the existing introducer sheath. After insertion, the distal tip of the Cardiva Catalyst wire is deployed, which opens a 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.

Device Name: Catalyst™ II System

Indications for Use:

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

Device Name: Catalyst™ III System with Protamine Sulfate

Indications for Use:

The Catalyst™ III System with Protamine Sulfate is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression in heparinized patients. The 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.

Comparison to Predicate Device:

No change is being made to the predicate device. The subject device is identical to the previously cleared device Catalyst™ II and III (K072297 and K082930). The only change that is being made is the addition of a Contraindication for Shell Fish Allergy.

Summary:

The Cardiva Medical Catalyst II System and Catalyst™ III System with Protamine Sulfate is identical to the previously cleared device Catalyst™ II and III (K072297 and K082930). The only change that is being made is the addition of a Contraindication for Shell Fish Allergy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2013

Cardiva Medical, Inc.
c/o Mr. Michael A. Daniel
Acting Vice President, Regulatory Affairs
888 W. Maude Ave.
Sunnyvale, CA 94085

Re: K130124
Trade/Device Name: Cardiva Catalyst™ II and III
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: January 23, 2013
Received: January 24, 2013

Dear Mr. Daniel:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

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

Enclosure

Section 7. Indications for Use Statement

510(k) Number (if known): K130124

Device Name: Catalyst™ II System

Indications for Use:

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

Device Name: Catalyst™ III System with Protamine Sulfate

Indications for Use:

The Catalyst™ III System with Protamine Sulfate is intended to promote hemostasis at arteriotomy sites as an adjunct to manual compression in heparinized patients. The 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.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner