K090872

1 of 2

510(k) Summary

APR 21 2009

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	
Date Prepared	March 26, 2009
Applicant Information	Cardica, Inc. 900 Saginaw Redwood City, California 94063 Main: 650-364-9975 Fax: 650-331-7195
Contact Person	Kimberlee Leon Office: 650-331-7119 Fax: 650-331-7195 e-mail: leon@cardica.com
Establishment Registration Number	3004114958
Device Information	Classification Name: Clip, Implantable Regulation Number: 21 CFR §878.4300 Trade Name: Cardica® C-Port® xA™ PLUS™ Distal Anastomosis System Common Name: Cardiovascular Surgical Instruments
Predicate Device(s)	Cardica® C-Port® xA™ Distal Anastomosis System (K063644)
Device Description	The Cardica® C-Port® xA™ PLUS™ Distal Anastomosis System is a sterile, single use device for creation of a reliably patent end-to-side anastomosis between a conduit and a small vessel. The product consists of accessories to assist in the conduit loading and a device that completes the anastomosis with stainless steel clips. Once the conduit has been loaded onto the device and the device positioned against the target vessel, the anastomosis is created by pushing the actuation button.

Intended Use	The Cardica® C-Port® xA™ PLUS™ Distal Anastomosis System is intended for the creation of anastomoses in blood vessels and grafts, including use in coronary artery bypass grafting procedures.
Comparison to Predicate Device	The Cardica® C-Port® xA™ PLUS™ Distal Anastomosis System is substantially equivalent to the Cardica® C-Port® xA™ Distal Anastomosis System (K063644, 21 CFR §878.4300). The subject device is substantially equivalent to the predicate device with regard to the intended use, device characteristics, method of use, materials, labeling, sterilization method and biocompatibility.
Device Testing Results and Conclusion	All necessary *in vitro* and *in vivo* testing has been performed on the C-Port® xA™ PLUS™ Distal Anastomosis System to ensure substantial equivalence to the predicate device, and to ensure the safety and effectiveness of the device.
Substantial Equivalence Summary	Cardica® C-Port® xA™ PLUS™ Distal Anastomosis System has the same indications for use and the same technological characteristics as the predicate device (K063644). This premarket notification has described the characteristics of the modified device in sufficient detail to assure substantial equivalence.
Conclusions	This Special 510(k) for Device Modification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2009

Cardica®, Inc.
c/o Ms. Kimberlee Leon
Manager, Quality Systems
900 Saginaw Drive
Redwood City, CA 94063

Re: K090872
C-Port® xA™ PLUS Anastomosis System
Regulation Number: 21 CFR 878.4300
Regulation Name: Clip, Implantable and Delivery System
Regulatory Class: Class II
Product Code: FZP
Dated: March 26, 2009
Received: March 30, 2009

Dear Ms. Leon:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Statement

510(k) Number:
(if known) K090872

Device Name: Cardica® C-Port® xA™ PLUS™ Distal Anastomosis System

Indications for Use: The Cardica® C-Port® xA™ PLUS™ Distal Anastomosis System is intended for the creation of anastomoses in blood vessels and grafts, including use in coronary artery bypass grafting procedures.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR§801.109) (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090872