K053524

Attachment 4

NOV 16 2006

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	
Date Prepared	15 December 2005
Applicant Information	Cardica, Inc. 900 Saginaw Redwood City, California 94063 Main: 650-364-9975 Fax: 650-364-3134
Contact Person	David Casal, PhD Office: 650-331-7145 Fax: 650-364-3134 e-mail: casal@cardica.com
Establishment Registration Number	3004114958
Device Information	Classification Name: Clip, Implantable Regulation Number: 21 CFR §878.4300 Trade Name: Cardica® C-Port® Anastomosis System Common Name: Cardiovascular Surgical Instruments
Predicate Device(s)	Cardica® C-Port® Anastomosis System (K040832)
Device Description	The Cardica® C-Port® 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 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 Anastomosis System is substantially equivalent to the Cardica® C-Port® Anastomosis System (K040832, 21 CFR §878.4300). The subject device is substantially equivalent to the predicate device with regard to indications, device characteristics, method of use, labeling and materials.
Device Testing Results and Conclusion	All necessary *in vitro* and *in vivo* testing has been performed on the C-Port® xA Anastomosis System and packaging to ensure substantial equivalence to the predicate device and to ensure the safety and effectiveness of the device.
Summary	Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the Cardica® C-Port® Anastomosis System has been shown to be substantially equivalent to the currently marketed predicate device.

Cardica® and C-Port® are registered trademarks of Cardica, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2006

Tiffini Lalude
Director of Regulatory Affairs
Cardica, Inc.
900 Saginaw Drive
Redwood City, CA 94063

Re: K053524
C-Port™ xA Distal Anastomosis System
Regulation Number: 21 CFR 878.4300
Regulatory Class: Class II
Product Code: FZP
Dated: October 1, 2006
Received: October 4, 2006

Dear: Ms. Lalude:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent to 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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket 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. An 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, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA.

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 (240) 276-0120. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 at (240) 276-3150.

Sincerely yours,

Donna R. Lachman

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

Attachment 2

Indications for Use Statement

510(k) Number: (if known) K053524

Device Name: Cardica® C-Port® xA Anastomosis System

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the Counter Use _____

(per 21 CFR §801.109 (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices