K070548

MAR 2 9 2007

Attachment 3

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	February 21, 2007
Applicant Information	Cardica, Inc. 900 Saginaw Redwood City, California 94063 Main: 650-364-9975 Fax: 650-331-7193
Contact Person	Tiffini Lalude Office: 650-331-7153 Fax: 650-331-7193 e-mail: lalude@cardica.com
Establishment Registration Number	3004114958
Device Information	Classification Name: Clip, Implantable Regulation Number: 21 CFR §878.4300 Trade Name: Cardica® C-Port® FlexA™ Distal Anastomosis System Common Name: Cardiovascular Surgical Instruments
Predicate Device(s)	Cardica® C-Port® xA™ Distal Anastomosis System (K053524 and K063644)
Device Description	The Cardica® C-Port® FlexA™ Distal Anastomosis System is a sterile, single use device for creation of a compliant end-to-side anastomosis between a graft vessel and target vessel. The product consists of a delivery device that holds the graft and deploys the pre-loaded clips, and the implantable stainless steel clips. Once the graft has been loaded onto the device and the device positioned against the target vessel, the arteriotomy and anastomosis are simultaneously created by pushing the

	actuation button.
Intended Use	The Cardica® C-Port® FlexA™ 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 FlexA™ Distal Anastomosis System is substantially equivalent to the Cardica C-Port xA™ Distal Anastomosis System; (K053524 and K063644, 21 CFR §878.4300). The deployment device design has been modified to allow the user the option of an anastomosis device with a flexible shaft and remote graft clamp actuators. The subject device is substantially equivalent to the predicate device with regard to indications, scientific technology, operation principles, basic device design and size, shelf life, packaging and sterilization materials and processes.
Device Testing Results and Conclusion	All necessary verification testing has been performed on the C-Port® FlexA™ Distal Anastomosis System to assure substantial equivalence to the predicate device and to assure the safety and effectiveness of the device. Based on the results of risk assessment and verification/validation testing the modifications to the FlexA System raise no new safety or efficacy issues.
Summary	Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the C-Port® FlexA™ Distal Anastomosis System has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2007

Cardica, Inc.
c/o Tiffini Lalude
Director, Regulatory Affairs
Redwood City, CA 94063

Re: K070548
Trade/Device Name: Cardica C-Port FlexA Distal Anastomosis System
Regulation Number: 21 CFR 878.4300
Regulation Name: Clip, Implantable
Regulatory Class: Class II
Product Code: FZP
Dated: February 21, 2007
Received: February 26, 2007

Dear Ms. Lalude:

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 (240) 276-0120. 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 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,

B Zuckerman for

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

Enclosure

Attachment 1

Indications for Use Statement

510(k) Number: (if known) K070548

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

Indications for Use: The Cardica® C-Port® FlexA™ Distal 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 X OR Over-the Counter Use_____

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070548