K073304

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	21 November 2007
Applicant Information	Cardica, Inc. 900 Saginaw Redwood City, California 94063 Main: 650-364-9975 Fax: 650-364-3134
Contact Person	Iskra Mrakovic Office: 650-331-7153 Fax: 650-364-3134 e-mail: mrakovic@cardica.com
Establishment Registration Number	3004114958
Device Information	Classification Name: Clip, Implantable Regulation Number: 21 CFR §878.4300 Trade Name: Cardica® C-PORT® X-CHANGE™ Anastomosis System Common Name: Cardiovascular Surgical Instruments
Predicate Device(s)	Cardica® C-Port® xA™ Anastomosis System (#K063644)
Device Description	The Cardica® C-PORT® X-CHANGE™ 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 delivers a series of clips that create an anastomosis between a small target vessel (e.g. coronary artery) and a conduit (e.g. saphenous vein graft). The stainless steel clips create a complete end-to-side anastomosis which is functionally equivalent to a hand-sutured, interrupted stitch anastomosis. The system consists of one (1) C-PORT® HANDLE X-CHANGE™ with up to three (3) C-PORT® xA™ X-CHANGE™ subassemblies and one (1) Retractor Mount.

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Intended Use	The Cardica® C-PORT® X-CHANGE™ 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® X-CHANGE™ ANASTOMOSIS SYSTEM is substantially equivalent to the Cardica® C-Port® xA™Anastomosis System (#K063644, 21 CFR §878.4300). The subject device is substantially equivalent to the predicate device with regard to 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® X-CHANGE™ ANASTOMOSIS SYSTEM and its packaging to ensure substantial equivalence to the predicate device, and to ensure the safety and effectiveness of the device.
Substantial Equivalence Summary	Cardica® C-PORT® X-CHANGE™ 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. For the few characteristics that may not be precise enough to ensure equivalence, performance data was collected, and this data demonstrates substantial equivalence. In keeping with the format of a Special 510(k) for Device Modification, performance data were not included in the submission, but the declarations provide certification that the data demonstrate 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

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Cardica, Inc.
c/o Ms. Iskra Mrakovic
Manager, Regulatory Affairs
900 Saginaw Drive
Redwood City, CA 94063

Re: K073304
Cardica® C-Port® X-Change™ Anastomosis System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: November 21, 2007
Received: November 23, 2007

Dear Ms. Mrakovic:

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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.
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) K073304

Device Name: Cardica® C-PORT® X-CHANGE™ ANASTOMOSIS SYSTEM

Indications for Use: The Cardica® Cardica® C-PORT® X-CHANGE™ 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___ (Part 21 CFR§801.109) OR Over-The-Counter Use _____ (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)

(Division Sign-Off)
Division of Cardiovascular
510(k) Number K073304