K101018

JUN 25 2010

F. 510(k) Summary

C-Port xA Hybrid Distal Anastomosis System

510(k) Number	
Date Prepared	April 9, 2010
Applicant Information	Cardica, Inc. 900 Saginaw Redwood City, California 94063 Main: 650-364-9975 Fax: 650-331-7195
Contact Person	Matthew E. Chroust, Director of QA/RA Office: 650-331-7152 Fax: 650-331-7195 e-mail: *chroust@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
Legally Marketed Predicate Device(s)	Cardica® C-Port® xA PLUS Distal Anastomosis System (K090872) April 21, 2009

Labeling and Intended Use	The subject 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. This is the same intended use as previously cleared for the predicate C-Port® xA PLUS Distal Anastomosis System (K090872). Draft Instructions for Use can be found in Section E, *Labeling*, of this submission. A redline showing the differences is also provided for reference. The Indications for Use statement can be found in Section H, *Indications for Use*. There is no change to the Product Label.
Device Description	The Cardica® C-Port® xA Plus Distal Anastomosis System delivers a series of clips that create an anastomosis between a small target vessel (e.g. coronary artery) and conduit (e.g. saphenous vein graft). An array of metal clips creates a complete, end-to-side anastomosis that is functionally equivalent to a hand-sutured interrupted stitch anastomosis. The system consists of one Anastomosis Device and one Retractor Mount
Indications for Use	The C-Port® xA Hybrid Plus Anastomosis System is is intended for use in the creation of anastomoses in blood vessels and grafts, including use in coronary artery bypass grafting procedures. The change in materials described above do not impact the Indications for Use, therefore no changes will be made to this labeling.

Comparison to Predicate Device	The subject Cardica® C-Port® xA Plus Distal Anastomosis System, is substantially equivalent to the predicate Cardica® C-Port® xA PLUS Distal Anastomosis System, which was cleared by FDA on April 21, 2009 (K090872) 1. Like its predicate device, the subject 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 (graft vessel) and target vessel. 2. Both products consist of sub-assemblies for stabilizing and positioning the conduit for grafting and for creating the anastomosis by deployment of an array of metal clips. 3. Once the graft vessel has been loaded onto the device and the device positioned against the target vessel, the anastomosis between the graft and target vessel is completed by pushing the actuation button. Modifications improving the reliability, manufacturability and appearance of the predicate device included the following: 1. Knife Component material changes from Stainless Steel to Nitinol for durability; 2. Heel Clip Component material changes from Stainless Steel to Titanium To reduce the force required to clamp. 3. Cartridge Housing Component material changes with the addition of pink and blue colorant for aesthetics; 4. A Cardica logo graphic is added to the Activation Knob Component via pad printing for better market recognition, and the material of the the Activation Knob Component changes from glass-filled polycarbonate to glass-filled nylon for durability.

	5. The Anvil Base Component material changes from machined type 416 Stainless steel to metal-injection molded (MIM) 17-4 Stainless steel to improve manufacturability. Adding Dicronite, a dry lubricant to the Anvil Base Component's cable channels reduces friction in the cable system. 6. Anvil Hinge Component material is changed, adding carbon filling to the Victrex PEEK material for increased dimensional stability.
Device Testing Results and Conclusion	All the aforementioned modifications have been rigorously verified and validated using Cardica's Design Control process (Cardica procedures WD-0400 and 0401): A Design Change Impact Analysis identified the system level ramifications of changes to materials and provided guidance and rationale for the selection of appropriate component and system level qualifications. A battery of tests and evaluations was performed to assess the impact of the component material changes identified above to ensure that these modifications do not alter the validity of *in vitro* and *in vivo* testing and other design validation activities previously performed on the predicate Cardica® C-Port® xA PLUS Distal Anastomosis System and its packaging to ensure substantial equivalence to the predicate device, and to ensure the safety and effectiveness of the device. Risk Management File review and Clinical Risk Benefit Analysis were conducted to ensure the continued safety and efficacy of the device. A detailed description of these changes is available in Section D, *Summary of Design Controls*.
Technological	See Device Description above.

Characteristics	
Substantial Equivalence Summary	Both the subject Cardica® C-Port® xA PLUS Distal Anastomosis System and its predicate have the same Indications for Use and the same technological characteristics as the predicate device C-Port xA PLUS (K090872). This premarket notification has described the characteristics of the modified device in sufficient detail to assure substantial equivalence. The subject C-Port® xA PLUS Distal Anastomosis System has the following similarities to those previously described and cleared for the predicate device: 1. same indicated use, 2. same operating principle, 3. same basic device design and size, 4. same materials (with the exception of those changes identified above), 5. same manufacturing processes, 6. same packaging and sterilization materials, 7. Instructions for Use are essentially identical, with the only changes being the model name and the clarification in the System Description of the Clip array construction being Stainless Steel and Nitinol in the Subject C-Port xA PLUS, where they had been Stainless Steel in the predicate.
Conclusions	In summary, the subject C-Port® xA PLUS Distal Anastomosis System described in this submission is substantially equivalent to the predicate device. 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 25 2010

Cardica, Inc.
c/o Mr. Matthew E. Chroust
Director, Quality & Regulatory Affairs
900 Saginaw Drive
Redwood City, CA 94063

Re: K101018
Trade/Device Name: Cardica® xA™ PLUS Distal Anastomosis System
Regulation Number: 21 CFR 878.4300
Regulation Name: Clip, Implantable and Delivery System
Regulatory Class: Class II
Product Code: FZP
Dated: May 27, 2010
Received: May 28, 2010

Dear Mr. Chroust:

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,

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

Enclosure

K161018

Indications for Use Statement

510(k) Number:
(if known)

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___ (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 Devices
510(k) Number K161018