APPENDIX A 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.

A. Name, Address, Phone and Fax number of the Applicant

Cardica, Inc.
900 Saginaw Drive
Redwood City, CA 94063
Telephone: (650)-364-9975
Fax: (650)-364-3134

B. Contact Persons

Sevrina Ciucci
Senior Regulatory Affairs Associate
Telephone: (650)-331-7147
Fax: (650)-331-3134

C. Date Prepared

March 29, 2004

D. Device Name

Trade Name: Cardica® C-Port™ Anastomosis System
Classification Name: Cardiovascular Surgical Instruments

E. Device Description

The Cardica® C-Port™ Anastomosis System is a sterile, single-patient use device. The Cardica® C-Port™ Anastomosis System is designed to create a reliable and consistent end-to-side anastomosis between a conduit and a small vessel. The product consists of accessories to assist in 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 an actuation button.

F. Intended Use

The C-Port™ Anastomosis System is intended for the creation of anastomoses in blood vessels and grafts, including use in coronary artery bypass grafting procedures.

G. Substantial Equivalence

The C-Port™ Anastomosis System is substantially equivalent to US Surgical Corporation's Auto Suture™ Modified VCS™ Clip™ Applier (K962043, 21 CFR 878.4800 and the Ethicon ENDOPATH™ and PROXIMATE™ Linear Cutters and Staplers (K020779, 21 CFR 878.4750), and the Coalescent Surgical U-Clip™ (K031623, K994160, 21 CFR 870.4300). The subject device is substantially equivalent to the predicate devices with regard to indications, device characteristics, method of use, labeling, and materials.

H. Device Testing Results and Conclusion

All necessary bench, animal, and clinical testing has been performed on the C-Port™ Anastomosis System and packaging to ensure substantial equivalence to the predicate devices and to ensure the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 2005

Cardica, Inc.
c/o Ms. Laurie Hook
Clinical Affairs Manager
900 Saginaw Drive
Redwood City, CA 94063

Re: K040832
Trade Name: Cardica® C-Port™ Anastomosis System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II (Two)
Product Code: FZP
Dated: August 09, 2005
Received: August 10, 2005

Dear Ms. Hook:

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 (301) 443-6597 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

APPENDIX F INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K040832

Device Name: Cardica® C-Port™ Anastomosis System

Indications For Use:

The Cardica® C-Port™ 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)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040832

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)
(Optional Format 1-2-9