DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 20, 2016

Cardica, Inc.
Mr. Greg Watson
Vice President of Operations
900 Saginaw Drive
Redwood City, California 94063

Re: K161137
Trade/Device Name: Dextera Microcutter 5/80™ Blue Reload, Dextera Microcutter 5/80™ Blue Curved Tip Reload, Dextera Microcutter 5/80™ White Reload, Dextera Microcutter 5/80™ White Curved Tip Reload
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: April 21, 2016
Received: April 22, 2016

Dear Mr. Watson:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161137

Device Name

Dextera MicroCutter 5/80™ Blue Reload; Dextera MicroCutter 5/80™ Curved Tip Blue Reload;
Dextera MicroCutter 5/80™ White Reload; Dextera MicroCutter 5/80™ Curved Tip White Reload

Indications for Use *(Describe)*

The MicroCutter 5/80 is intended for transection and resection in multiple open or minimally invasive urologic, thoracic, and pediatric surgical procedures, as well as application for transection, resection, and/or creation of anastomoses in the small and large intestine, and the transection of the appendix.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – Dextera MicroCutter 5/80™

A. Date Prepared

April 21, 2016

B. 510(k) Owner

Cardica, Inc.
900 Saginaw Drive
Redwood City, California 94063
Phone: 650-364-9975
Fax: 650-364-3134

C. Contact Person

Greg Watson
Vice President, Operations
(650) 331-7163 (office)
(949) 412-9808 (cell)
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D. Device Information

Trade name: Dextera MicroCutter 5/80™ Blue Reload, Dextera MicroCutter 5/80™ Blue Curved Tip Reload, Dextera MicroCutter 5/80™ White Reload and Dextera MicroCutter 5/80™ White Curved Tip Reload

Common name: Staple

Classification Name: Implantable staple

Regulation Number: 21 CFR §878.4750

Product Code: GDW

E. Marketed Predicate Devices

MicroCutter XCHANGE® 30 Blue Cartridge
MicroCutter XCHANGE® 30 Blue Curved Tip Cartridge
MicroCutter XCHANGE® 30 White Cartridge
MicroCutter XCHANGE® 30 White Curved Tip Cartridge
(K132581, K140118, K140170 and K151081)

F. Device Description

The size of the Dextera MicroCutter 5/80™ Blue Reload and Dextera MicroCutter 5/80™ Blue Curved Tip Reload staple is compatible with tissue that can be easily compressed to 1.5mm. The size of the Dextera MicroCutter 5/80™ White Reload and Dextera MicroCutter 5/80™ White Curved Tip Reload staple is compatible with tissue that can be easily compressed to 1.0mm. The cut length of the staple line is 28.0mm (1.10in) and the staple line length is 30mm long. The Dextera MicroCutter 5/80™

Reloads are deployed using the Dextera MicroCutter 5/80™ Stapler. The MicroCutter 5/80 Stapler is a single patient use stapler that delivers two, double staggered rows of 316L stainless steel staples while simultaneously transecting tissue between staple rows.

G. Intended Use

The MicroCutter 5/80™ is intended for transection and resection in multiple open or minimally invasive urologic, thoracic, and pediatric surgical procedures, as well as application for transection, resection, and/or creation of anastomoses in the small and large intestine, and the transection of the appendix.

H. Comparison to Predicate Device

The Dextera MicroCutter 5/80™ Blue Reload, Dextera MicroCutter 5/80™ Blue Curved Tip Reload, Dextera MicroCutter 5/80™ White Reload and Dextera MicroCutter 5/80™ White Curved Tip Reload have minor modifications in comparison to the legally marketed predicate devices. The primary design changes include two minor modifications to the Reloads. These modifications were done to minimize interference and provide a better fit with other Reload components, and to help ensure the Reload is secured within the Stapler. The modifications do not alter the fundamental scientific technology and or intended use of the devices.

I. Non-Clinical Performance Data

Bench testing, including staple forming and release, cartridge loading force, cartridge unloading force, cartridge boss strength, cartridge retention during and outside of deployment, dimensional inspection, leak/burst pressure testing, staple form height, and deployment force, was performed.

J. Conclusion

Bench testing was conducted to verify the performance of the staple. The results demonstrated that the subject devices perform as intended and are substantially equivalent to the predicate devices.