510(k) Summary – MicroCutter XCHANGE™ 30 White Cartridge (K140170)

FEB 19 2014

A. Date Prepared

January 22, 2014

B. Applicant Information

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C. Contact Person

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D. Establishment Registration Number

3004114958

E. Device Information

Common, Usual or Classification Name: Staple, Implantable
Regulation Number: 21 CFR §878.4750
Product Code: GDW

F. Trade Name

MicroCutter XCHANGE™ 30 White Cartridge

G. Legally Marketed Predicate Device(s)

MicroCutter XCHANGE™ 30 (K132581)

H. Device Description

The MicroCutter XCHANGE™ 30 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. The MicroCutter XCHANGE™ 30 White Cartridge is available for deployment with the MicroCutter XCHANGE ™ 30 Stapler and delivers a staple (2.8mm) compatible with tissue that can be compressed to 1.0mm. The staple line is approximately 30mm long with a transection length of approximately 27mm.

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I. Indications for Use

The MicroCutter XCHANGE™30 is intended for use in multiple open or minimally invasive surgical procedures for the transection, resection, and/or creation of anastomoses in small and large intestine as well as the transection of the appendix.

J. Comparison to Predicate Device

The subject MicroCutter XCHANGE™ 30 White Cartridge is equivalent in its Indications for Use to the predicate MicroCutter XCHANGE™ 30 Blue Cartridge (K132581). The difference between the subject White Staple Cartridge and the predicate Blue Staple Cartridge are as follows:

1. Removal of the colorant from the plastic material used at the distal tip of the cartridge,
2. Decrease of primary and secondary staple tine length on the implant, and
3. The proximal end of the subject MicroCutter XCHANGE™ 30 White Cartridge adds an index ridge feature so the Stapler can differentiate between the two Cartridges.

K. Technological Characteristics

The technological characteristics of the subject MicroCutter XCHANGE™ 30 White Cartridge are substantially equivalent to the predicate device as demonstrated through verification testing.

The subject MicroCutter XCHANGE™ 30 White Cartridge has similar features as compared to the predicate device as shown in table below:

Feature	PREDICATE DEVICE MicroCutter XCHANGE 30 Blue Cartridge (K132581)	SUBJECT DEVICE MicroCutter XCHANGE 30 White Cartridge
Staple		
Staple Material	Stainless steel (316L)	Same as predicate device
Staple Thickness	0.19mm	Same as predicate device
Unformed Staple height	1.83mm	1.82mm
Unformed Staple Primary Tine Length	3.43mm	1.81mm
Unformed Staple Secondary Tine Length	0.56mm	0.30mm
Formed Staple Height	1.4mm (compatible with tissue thickness that can be compressed easily to 1.50mm)	1.16mm (compatible with tissue thickness that can be compressed easily to 1.00mm)
Formed Staple Configuration	D shaped	Same as predicate device

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Feature	PREDICATE DEVICE MicroCutter XCHANGE 30 Blue Cartridge (K132581)	SUBJECT DEVICE MicroCutter XCHANGE 30 White Cartridge
Intended tissue thickness	Compatible with tissue thickness that can be compressed easily to 1.50mm	Compatible with tissue thickness that can be compressed easily to 1.00mm
Staple Line Configuration	Two (2), double-staggered rows	Same as predicate device
Staple Line Length	30mm	Same as predicate device
Number of Staples Per Deployment	50 (One row of 13 and one row of 12 on either side of transaction line)	Same as predicate device
MRI Compatibility	MR-Conditional	Same as predicate device
Staple Cartridge		
Staple Cartridge Insert	Vectra A130 Liquid Crystal Polymer (LCP) with VG3010K20 Blue colorant, and Stainless Steel	Vectra A130 Liquid Crystal Polymer (LCP) with no colorant, and Stainless Steel
Biocompatibility		
Material Biocompatibility (Delivery Device, Staple Cartridge and Staple)	All components of the Cardica MicroCutter XCHANGE 30 are comprised of materials that were deemed acceptable in accordance with ISO Standard 10993-1. Biocompatibility: Cytotoxicity, Sensitization, Irritation, Toxicity, Hemocompatibility	Same as predicate device
Staple Cartridge Packaging, Sterilization and Shelf Life		
Packaging	Tyvek and Nylon/LDPE/HDPE coextrusion film Pouch	Same as predicate device
Sterilization	Gamma radiation	Same as predicate device
Sterility Assurance Level	10^{-6}	Same as predicate device
Shelf Life	12 months	Same as predicate device
Performance		
Tissue Leak Pressure (Bench)	The subject White Staple Cartridge is non-inferior and substantially equivalent to the predicate Blue Staple Cartridge	
Staple line pull-apart strength	8.2 +/- 0.9 lb.	11.5 +/- 1.2 lb.

L. Non-Clinical Performance Data

This modification was verified through design verification testing. Bench and animal testing was conducted and the results demonstrated substantial equivalence to the predicate device, and the MicroCutter XCHANGE™ 30 White Cartridge met all design specifications. A summary of the design requirements evaluated were as follows:

- Reliability testing was completed and demonstrated that device performance and strength meets design specification, post gamma sterilization, transit conditioning, environmental conditioning, and accelerated aging.
- Shelf life testing was completed and passed in accordance with ASTM F1980.
- Biocompatibility testing was completed and passed in accordance with ISO 10993-1 requirements.
- A chronic, pre-clinical evaluation of small intestinal anastomoses created in juvenile pigs by the white and blue staples, using the MicroCutter XCHANGE™ 30 Stapler, was performed and demonstrated substantial equivalence of the subject White Staple Cartridge to the predicate Blue Staple Cartridge.

M. Clinical Performance

There are no changes to the indications for use, so the subject White Staple Cartridge was fully verified and validated through design testing described in Section L above.

N. Conclusions

The subject MicroCutter XCHANGE™ 30 White Cartridge has been carefully compared to a legally marketed device, MicroCutter XCHANGE™ 30 Blue Cartridge, with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to verify the performance of the device and ensure the MicroCutter XCHANGE™ 30 White Cartridge functions as intended and meets all design specifications. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 19, 2014

Cardica, Inc.
Vee Arya
Senior QA/RA Manager
900 Saginaw Drive
Redwood City, California 94063

Re: K140170
Trade/Device Name: MicroCutter XCHANGE™ 30 White Cartridge
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: January 22, 2014
Received: January 23, 2014

Dear Vee Arya:

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,

David Krause -S

for Binita Ashar, MD, MBA, FACS
Acting 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 on last page.

510(k) Number *(if known)*
K140170

Device Name
MicroCutter XCHANGE™ 30 White Cartridge

Indications for Use *(Describe)*
The MicroCutter XCHANGE™30 is intended for use in multiple open or minimally invasive surgical procedures for the transection, resection, and/or creation of anastomoses in small and large intestine as well as 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S

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