



January 15, 2016

Cardica Incorporated
% Ms. Cindy Domecus
Domecus Consulting Services, LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K151081

Trade/Device Name: Cardica MicroCutter XCHANGE® 30
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: December 14, 2015
Received: December 15, 2015

Dear Ms. Domecus:

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

Indications for Use

510(k) Number (if known)

K151081

Device Name

Cardica MicroCutter XCHANGE® 30

Indications for Use (Describe)

The MicroCutter XCHANGE® 30 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 – Cardica MicroCutter XCHANGE® 30

A. Date Prepared

January 12, 2016

B. 510(k) Owner

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C. Contact Person

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D. Device Information

Trade name: MicroCutter XCHANGE® 30 White Cartridge and MicroCutter XCHANGE 30 White Curved Tip Cartridge

Common name: Staple

Classification Name: Implantable staple

Regulation Number: 21 CFR §878.4750

Product Code: GDW

E. Legally Marketed Predicate Devices

Ethicon PROXIMATE Vascular Linear Cutter 55 (K020779)
Ethicon ENDOPATH ETS-Flex45 Endoscopic Linear Cutters (K002398)

F. Device Description

The MicroCutter XCHANGE® 30 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 size of the White Cartridge staple is compatible with tissue that can be easily compressed to 1.0mm. The staple line is approximately 30mm long with a transection length of approximately 27mm.

G. Intended Use

The MicroCutter XCHANGE® 30 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 Cardica MicroCutter XCHANGE® 30 is a cartridge based stapling device with a 5mm diameter shaft, capable of unlimited rotation and articulation up to 160° (80° in each direction) in 20° increments. The predicate devices are also cartridge based, offering shaft rotation of 360°. The primary predicate does not articulate (0°) and the secondary predicate is capable of articulation up to 70° (35° in each direction).

The Cardica MicroCutter XCHANGE® 30 delivers a 30mm staple line consisting of two double-staggered rows (4 rows total) of D-shaped staples constructed of 316L stainless steel. The outermost rows contain 12 staples each, while the inner rows contain 13 staples each, for a total of 50 staples. The primary predicate device delivers a 60mm staple line, consisting of two double-staggered rows (4 rows total) of B-shaped staples constructed of titanium. The secondary predicate device delivers a 45mm staple line, consisting of two triple-staggered rows (6 rows total) of B-shaped staples constructed of titanium.

The Cardica MicroCutter XCHANGE® 30 has similar features as compared to the predicate devices as shown in the table below:

Feature	MicroCutter XCHANGE® 30 (K132581)	Ethicon PROXIMATE Vascular Linear Cutter 55 (K020779) (Primary Predicate)	Ethicon ENDOPATH ETS-Flex45 Endoscopic Linear Cutters (K002398) (Secondary Predicate)
Deployment Device			
Deployment	Cartridge based deployment (up to 6 deployments per tool) for single patient use	Cartridge based deployment (up to 8 deployments per tool) for single patient use	Cartridge based deployment for single patient use
Shaft Length	340 mm	78 mm	340 mm
Transection Line Length	27 mm	53 mm	41 mm

Feature	MicroCutter XCHANGE® 30 (K132581)	Ethicon PROXIMATE Vascular Linear Cutter 55 (K020779) (Primary Predicate)	Ethicon ENDOPATH ETS-Flex45 Endoscopic Linear Cutters (K002398) (Secondary Predicate)
End-Effector Opening	5.3mm at tissue stop (proximal); 16.7mm at distal opening	Variable – two halves separate allowing end-effector to have as large of an opening as user requires	2.6mm at tissue stop (proximal); 12.3mm at distal opening
Shaft Rotation	360°	Same as subject device	Same as subject device
Articulation	160° (80° each direction)	0° (no articulation)	70° (35° each direction)
Staple			
Staple Material	Stainless steel (316L)	Titanium	Titanium
White Unformed Staple height	1.82 mm	2.5 mm	2.5 mm
White Formed Staple Height	1.16 mm (compatible with tissue thickness that can be compressed easily to 1.0 mm)	1.0 mm (compatible with tissue thickness that can be compressed easily to 1.00 mm)	1.0 mm (compatible with tissue thickness that can be compressed easily to 1.00 mm)
Formed Staple Configuration	D shaped	B shaped	B shaped
Staple Line Configuration	Two (2), double-staggered rows	Two (2), double-staggered rows	Three (3), double-staggered rows
Staple Line Length	30 mm	55 mm	45 mm
Number of Staples Per Deployment	50 (One row of 13 and one row of 12 on either side of transection line)	56 (for the 55 mm staple line length)	66 (one row of 11, one row of 11, and one row of 11 on either side of transection line)
MRI Compatibility	MR-Conditional	Same as subject device	Same as subject device
Biocompatibility			
Material Biocompatibility (Delivery Device 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.	Same as subject device	Same as subject device
Packaging, Sterilization and Shelf Life			
Packaging	Thermoformed tray with Tyvek lid	Thermoformed tray with Tyvek lid	Thermoformed tray with Tyvek lid
Sterilization Sterility Assurance Level	Gamma radiation, 10 ⁻⁶	Gamma radiation, Not Available	Gamma radiation, Not Available
Shelf Life	24 months	Not Available	Not Available

Feature	MicroCutter XCHANGE® 30 (K132581)	Ethicon PROXIMATE Vascular Linear Cutter 55 (K020779) (Primary Predicate)	Ethicon ENDOPATH ETS-Flex45 Endoscopic Linear Cutters (K002398) (Secondary Predicate)
Performance			
Tissue Burst Pressure White in Porcine Carotid Artery (Bench)	No statistical difference, $p > 0.05$		Not Available
Tissue Burst Pressure White in Porcine Jugular Vein (Bench)	No statistical difference, $p > 0.05$		Not Available

I. Non-Clinical Performance Data

Bench testing in the form of Tissue Burst pressure testing was conducted and the results demonstrated substantial equivalence to the predicate devices.

Cardica also performed two chronic animal studies for abdominal and intrathoracic vascular transections: a study in which unilateral nephrectomies were performed and a study in which unilateral lobectomies were performed. In these chronic animal studies, the Cardica subject staple was compared to the Ethicon predicate staple.

All animals had an uncomplicated 5-week postoperative course and were euthanized after a second terminal surgery. The vascular and ureter stumps were all unremarkable without any signs of postoperative bleeding or infection. The histologic evaluation was also unremarkable and showed no demonstrable difference between the two groups. The endpoints of the studies were met.

J. Conclusion

Bench testing and chronic animal studies were conducted to validate the performance of the staple. The results demonstrated that the subject device is substantially equivalent to the predicate devices.