JAN - 7 2014

510(k) Summary – Cardica MicroCutter XCHANGE™ 30

A. Date Prepared
January 2, 2014

B. Applicant Information
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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

G. Legally Marketed Predicate Device(s)
Autosuture™ ENDO GIA™ Universal Stapler (K111825)
Ethicon Proximate™ and Endopath™ Linear Staplers (K020779)

H. 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 staple (blue; 3.5mm) is compatible with tissue that can be compressed to 1.5mm. The staple line is approximately 30mm long with a transection length of approximately 27mm.

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 Cardica MicroCutter XCHANGE™ 30 is substantially equivalent in its Indications for Use to the Covidien Autosuture™ ENDO™ GIA Stapler (K111825) and Ethicon Proximate™ Linear Staplers (K020779) in regards to the predicates' use for the transection, resection, and/or creation of anastomoses in surgical procedures involving gastrointestinal tissue.

The Cardica MicroCutter XCHANGE™ 30 is substantially equivalent in design and performance specifications to the Covidien Autosuture™ ENDO™ GIA Universal Stapler trigger handle, shaft and end-effecter function (K111825) and the Ethicon Proximate™ Linear Cutters' and Staplers' staple cartridge (K020779).

K. Technological Characteristics

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° degrees in each direction) in 20° increments. Predicate devices are also cartridge based, offer varying amounts of shaft rotation (90° to unlimited rotation) and less articulation range (80° – 90° total compared to 160°).

The MicroCutter XCHANGE™ 30 Blue Cartridge delivers a 30mm staple line consisting of two double-staggered rows (4 rows total) of D-shaped staples constructed of medical grade 316L stainless steel. The outermost rows contain 12 staples each, while the inner rows contain 13 staples each, for a total of 50 staples. Predicate devices can be used with various cartridges to deliver titanium staples ranging from 30 – 90mm, consisting of either two, double-staggered rows (4 rows total) or two, triple staggered rows (6 rows total).

One of the primary differentiating factors in the design of the MicroCutter XCHANGE™ 30 staple is that the staples are medical grade 316L stainless steel, which is a higher strength material than titanium or titanium alloy used in other stapling products. Current B-shaped staples are formed by buckling the tines. The forces required to accomplish the buckling typically represent the peak forces during staple formation. The MicroCutter XCHANGE™ 30 uses a guided, rotating form. The motion through the tissue is similar to that of a curved needle.

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

Feature	MicroCutter XCHANGE 30	ENDO GIA Universal (K111825)	PROXIMATE Linear Cutters and Staplers (K020779)
Deployment Device			
Deployment	Cartridge based deployment (up to 6 deployments per tool) for single patient use	Cartridge based deployment (up to 25 deployments per tool) for single patient use	Cartridge based deployment (up to 4-8 deployments per tool) for single patient use (excepting Access 55)
Shaft Length	340mm	325mm	Not available
Transection Line Length	27mm	30mm	Up to 100mm (depending on Cutter); Staplers do not cut (Staplers and Access 55)
End-Effector Opening	5.3mm at tissue stop (proximal); 16.7mm at distal opening	5.25mm at tissue stop (proximal); 16.45mm at distal opening	Adjustable parallel jaws (excepting Access 55)
Shaft Rotation	360°	Same as subject device	90°; 30° shaft flex (Access 55 only)
Articulation	160° (80° each direction)	90° on the roticulator model (45° each direction)	80° (Access 55 only)
Staple			
Staple Material	Stainless steel (316L)	Titanium	Titanium
Blue Unformed Staple height	3.22mm	3.50mm	3.50-3.85mm
Blue Formed Staple Height	0.75mm (compatible with tissue thickness that can be compressed easily to 1.50mm)	1.00mm (compatible with tissue thickness that can be compressed easily to 1.50mm)	1.00-1.50mm (compatible with tissue thickness that can be compressed easily to 1.00-2.50mm)
Formed Staple Configuration	D shaped	B shaped	B shaped
Staple Line	Two (2), double-	Two (2), triple-	Same as subject

Feature	MicroCutter XCHANGE 30	ENDO GIA Universal (K111825)	PROXIMATE Linear Cutters and Staplers (K020779)
Configuration	staggered rows	staggered rows	device
Staple Line Length	30mm	30mm, 45mm, 60mm	10 (Cutters only), 30, 55 (Cutters and Access 55), 60, 75 (Cutters only) and 90mm
Number of Staples Per Deployment	50 (One row of 13 and one row of 12 on either side of transaction line)	48 (for the 30mm staple line length)	58 and 74 (for the 30 and 55mm staple line)
MRI Compatibility	MR-Conditional	MR-Safe	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	PTFE tray with Tyvek lid	Thermoformed tray with Tyvek lid	Thermoformed tray with Tyvek lid
Sterilization Sterility Assurance Level	Gamma radiation 10^{-6}	Ethylene Oxide Not Available	Gamma radiation Not Available
Shelf Life	24 months	Not Available	Not Available
Performance			
Tissue Leak Pressure (Bench)	No statistical difference p>0.05		Not Tested
Tissue Leak Pressure (Animal)	No statistical difference p>0.05		Not Tested
Clinical Performance (*MicroCutter European Trial I (METI): The Cardica MicroCutter in Surgical Stapling*)	Non-inferior to composite historical control	Not Applicable	Not Applicable

L. Non-Clinical Performance Data

Bench and animal testing were conducted and the results demonstrated substantial equivalence to the predicate devices, and that the Cardica MicroCutter XCHANGE 30 met design specifications. A summary of the type of testing conducted is as follows:

- Integrity of the staple line was confirmed via dimensional analysis of the staples, visual inspection of the staple line, and through burst pressure testing of the staple line.
- Dimensional tests were conducted to confirm attributes for shaft diameter, jaw aperture, clamp gap, articulation angle, and staple line length.
- Ergonomics testing was conducted to confirm device ergonomics and usability for cartridge load/unload force, force to articulate, force to deploy, force reset device, and torque require to rotate device.
- Safety testing was completed to confirm the strength of the deploy lockout safety mechanism to prevent advancement of the knife when a cartridge is not properly loaded into the device.
- Functionality testing was completed to confirm device features for the clamp system, deployment system, and articulation.
- Reliability testing was completed and demonstrated that device performance does not degrade when deploying within the indicated number of clinical deployments.
- Packaging Validation testing was completed and passed in accordance with ASTM D4169.
- Sterilization testing was completed and passed in accordance with ISO11137-2.
- Bioburden testing was conducted and passed in accordance with ANSI/AAMI/ISO 11737-1:1995 Sterilization of Medical Devices- Microbiological Methods Part I: Estimation of Population of Microorganisms on Products.
- Shelf life testing was completed and passed in accordance with ASTM F1980.
- Biocompatibility testing was completed in accordance with ISO 10993-1 requirements. The following tests were completed and passed:
  - Cytotoxicity
  - ISO Intracutaneous Reactivity
  - Hemolysis (in vitro)
  - Sensitization
  - Acute Systemic Toxicity
  - Material Mediated Pyrogen (as required)
  - Coagulation (as required)
  - Thromboresistance (as required)

M. Clinical Study Information

The MicroCutter XCHANGE™ 30 System was evaluated in a prospective, open label, multi-center study with an All-Comers enrollment of subjects requiring surgical stapling of the stomach and/or intestine. 160 subjects were enrolled and followed postoperatively for at least 30 days. 423 deployments were performed. The primary endpoint was statistical non-inferiority of composite related severe adverse event rate (composite of infection, leakage, bleeding, and strictures) in study subjects when compared to composite severe adverse event rate (composite of infection, leakage, bleeding, and strictures) as derived from a comprehensive analysis of the medical literature with regards to the comparable open and laparoscopic procedure. One (1) composite severe adverse event (composite of infection (non-dermal), leakage, bleeding, and strictures) related to the MicroCutter XCHANGE™ 30 System was reported in a total of one hundred fifty three (153) patients (0.65%). The exact upper 95% confidence limit for this rate is 3.59%. Based on these results, the primary endpoint was met.

Additionally, there were 6 events reported for handsewn anastomoses and 6 events for other stapling devices in procedures in which the MicroCutter was used. These events do not factor into the calculation of the primary endpoint event rate for the MicroCutter. There is a procedural success rate of 91.5% (140/153) when the MicroCutter is used with other anastomoses modalities.

Stapler and Hand-sewn related Severe Adverse Events Categories	*Hand-sewn related*	*Other Stapler related*	*MicroCutter related*	Total N
Leakages	0	2	0	2
Bleedings	3	0	1	4
Infections	1	2	0	3
Strictures	0	1	0	1
Other Complications	2	1	0	3
Total	**6**	**6**	**1**	**13**

STAPLER AND HAND-SEWN ANASTOMOSIS RELATED PRIMARY ENDPOINT EVENTS

The following table depicts the tissue and number of deployments where the MicroCutter was used:

MicroCutter Tissue Use	All Sites N* (%)
Anastomose small intestine to stomach	1 (0.2)
Anastomosis of small intestine	25 (5.9)
Anastomosis of small intestine to colon	13 (3.1)
Closure of enterotomy	5 (1.2)
Transection of appendix	57 (13.5)
Transection of colon	81 (19.1)
Transection of common bile duct	1 (0.2)

MicroCutter Tissue Use	All Sites N* (%)
Transection of duodenum	19 (4.5)
Transection of Mesocolon/Mesoappendix	6 (1.4)
Transection of ovary	1 (0.2)
Transection of small intestine	213 (50.4)
Vascular transection	1 (0.2)
Total	**423**

*N = number of deployments

The following table depicts procedures by clinical approach:

	Total N* (%)
Observation	160 (N/A)
Open	70 (43.8)
Laparoscopic	75 (46.9)
Laparoscopic assisted	15 (9.4)
Converted	0 (0)

*N = number of observations

N. **Conclusions**

The MicroCutter XCHANGE™ 30 Stapler and Blue Cartridge have been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, clinical and non-clinical testing was conducted to validate the performance of the device and ensure the MicroCutter XCHANGE™ 30 Stapler and Blue Cartridge function as intended and meet design specifications. The comparison, clinical and non-clinical results demonstrate that the device is substantially equivalent to the predicate devices 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 20993-0002

January 7, 2014

Cardica Incorporated
Ms. Vee Arya
Senior Manager, Quality Assurance/Regulatory Affairs
900 Saginaw Drive
Redwood City, California 94063

Re: K132581
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: November 21, 2013
Received: November 27, 2013

Dear Ms. 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 contact 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. 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,

Binita S. Ashar -S
2014.01.07 16:32:32 -05'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132581

Device Name
Cardica®MicroCutter XCHANGE™ 30

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)*

David Krause -S