JUL 5 2013

Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K131511

1. Date of Submission: 04/07/2013

2. Sponsor Identification

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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: Disposable Circular Stapler
Disposable Linear Staplers and Reloads
Disposable Hemorrhoidal Stapler
Disposable Endoscopic Linear Cutter Staplers and Reloads
Disposable Linear Cutter Staplers and Reloads
Disposable Curved Cutter Stapler

Proposed Device Common Name: Staplers

Regulatory Information:
Classification Name: staple, implantable;
Classification: II;
Product Code: GDW;
Regulation Number: 21 CFR 878.4750;
Review Panel: General & Plastic Surgery;

Intended Use Statement:

The Disposable Circular Stapler have applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

The Disposable Linear Staplers and Reloads have application in the resection or transection of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.

The Disposable Hemorrhoidal Staple have application for general surgical treatment of hemorrhoids.

The Disposable Endoscopic Linear Cutter Staplers and Reloads have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

The Disposable Linear Cutter Staplers and Reloads have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the creation of anastomoses.

The Disposable Curved Cutter Stapler is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures.

5. Predicate Device Identification

510(k) Number: K120179
Product Name: REACH™ Surgical Staplers, including:
Circular Staplers with Staples,
Linear Staplers with Single Use Loading Units,
Procedure Sets for Prolapse and Hemorrhoids,
Endoscopic Linear Cutting Staplers with Single Use Loading Units,
Linear Cutting Staplers with Single Use Loading Units
Manufacturer: Reach Surgical, Inc.

510(k) Number: K091322
Predicate Device Name: CONTOUR™ Curved Cutter Stapler and Reloads
Manufacturer: Ethicon Endo-Surgery, LLC

6. Device Description

6.1 Disposable Circular Stapler

The proposed device, Disposable Circular Stapler is a sterilized and disposable surgical instrument intended to be used throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

It places a double staggered, circular row of titanium staples upon activation, which was achieved by squeezing the handles firmly as far as they could go. Immediately after formation of the staples, the excess tissue will be resected by the circular knife, and then a circular anastomosis is created.

The staple is available in two specifications which are 4.8 mm and 5.2 mm to be used per different thickness of the tissue.

6.2 Disposable Linear Staplers and Reloads

The proposed device, Disposable Linear Staplers and Reloads is a sterilized and disposable surgical instrument intended to be used in the resection or transection of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.

It places a double staggered row of titanium staples and is available in 30 mm, 45 mm, 60mm and 94 mm staple line length for use in various applications. Four staple sizes (3.8mm ,4.2 mm ,4.5 mm and 4.8 mm) are available to accommodate various tissue thicknesses. Each stapler could be reloaded no more than 7 times for total 8 firings.

The Disposable Linear Staplers and reloads have two configurations: (1) DLS serials are Disposable Linear Staplers and Reloads, and (2) DLR serials are reloads for Disposable Linear Staplers. Each of them has various specifications.

6.3 Disposable Hemorrhoidal Stapler

The proposed device, Disposable Hemorrhoidal Stapler is a sterilized and disposable surgical instrument, which has application for general surgical treatment of hemorrhoids.

It is a set of instruments that place a double staggered, circular row of titanium staples. Immediately after the formation of staples, the circular knife blade resects the excess of compressed mucosa. The sets are commonly used in the procedures for prolapsed and Hemorrhoids. They are also used for other applications when circular or semicircular stapling of anorectic tissue is required.

6.4 Disposable Endoscopic Linear Cutter Staplers and Reloads

The proposed device, Disposable Endoscopic Linear Cutter Staplers and Reloads is a sterilized and disposable surgical instrument, which has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

It places two, triple-staggered rows of titanium staples and simultaneously divides the tissue from central line. The size of the staples is decided by selecting 3.5 mm, or 4.8 mm reload. The Endoscopic Linear Cutter can be adapted for all of the reload sizes available.

The Disposable Endoscopic Linear Cutter Staplers and Reloads have two configurations: (1) DEC serials are Disposable Endoscopic Linear Cutter Staplers and Reloads, and (2) DER serials are reloads for Disposable Endoscopic Linear Cutter Staplers. Each of them has various specifications. Detail specifications are presented in ***Section 4.5 Model Description***.

6.5 Disposable Linear Cutter Staplers and Reloads

The proposed device, Disposable Linear Cutter Staplers and Reloads is a sterilized and disposable surgical instrument, which has application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the creation of anastomoses.

It places two double staggered rows of titanium staples and simultaneously cut and divides tissue between the two double rows. The Disposable Linear Cutter Staplers and Reloads are available in 55 mm, 75 mm, 80 mm and 100 mm lengths. Reloads are available in four staple sizes to accommodate

various tissue thicknesses: 3.8 mm, 4.0mm, 4.5mm and 4.8 mm.

The Disposable Linear Cutter Staplers and Reloads has two configurations: (1) DLC serials is Disposable Linear Cutter Staplers with Reloads, and (2) DCR serials is Reloads for Disposable Linear Cutter Staplers. Each of them has various specifications.

6.6 Disposable Curved Cutter Stapler

The proposed device, Disposable Curved Cutter Stapler is a sterilized and disposable surgical instrument, which is mainly suitable for low rectal resection, transection and anastomosis of tissues where manual anastomosis is difficult.

It places four staggered curved row of titanium staples on the tissue upon activation, and cut the tissue between staple lines.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. These tests include:

Performance Testing, including Physical Specification, Closed Staple Height Dimensions, Pressure Resistance Evaluation, Maximum Tensile Strength of Staple Line Repair and Force Required to Fire Stapler
Endotoxin Limit
Package Integrity, including internal pressure test, dye penetration tests and seal strength test
Shelf Lift

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

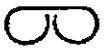
Table 3-1 Comparison of Disposable Circular Stapler

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The Disposable Circular Stapler have applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.	Same
Operation Principle	Manual	Same
Cutting Mechanism	Circular Knife	Same
Safety Mechanism	Indicator for appropriate range of desired closed staple height.	Same
	Safety Release for preventing from mis-firing.	Same
Outsider Diameter	21, 23, 25, 27, 29, 31, 33 mm	Similar
Cutting Diameter	12.4, 15, 17, 18.5, 20, 22.2, 24, mm	Similar
Number of Staples	18, 20, 22, 24, 28, 30	Similar
Closed Staples Height	2.0, 2.2 mm	Similar
Closed Staples Form		Same
Hardness (Circular knife)	≧380HV0.2	Same
Pressure Resistance after Suturing	≥3.6kPa	Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Similar
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

Difference in Outsider Diameter, Cutting Diameter, Number of Staples and Sterilization between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Disposable Circular Stapler, is determined to be Substantially Equivalent (SE) to the predicate device, Circular Staplers with Staples (K120179), in respect of safety and effectiveness.

Table 3-2 Comparison of Disposable Linear Staplers and Reloads

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The Disposable Linear Staplers and Reloads have application in the resection or transection of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.	Same
Operation Principle	Manual	Same
Safety Mechanism	Safety Release for preventing from mis-firing.	Same
Suture Line Length	30, 45, 60, 94 mm	Similar
Number of Staples	11, 15, 21, 33	Same
Closed Staples Height	1.5, 1.8 mm	Similar
Closed Staples Form		Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Similar
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

Difference in Suture Line Length, Closed Staples Height and Sterilization between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Disposable Linear Staplers and Reloads, is determined to be Substantially Equivalent (SE) to the predicate device, Linear Staplers with Single Use Loading Units (K120179), in respect of safety and effectiveness.

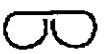
Table 3-3 Disposable Hemorrhoidal Stapler

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The Disposable Hemorrhoidal Staple have application for general surgical treatment of hemorrhoids.	Same
Operation Principle	Manual	Same
Cutting Mechanism	Circular Knife	Same
Safety Mechanism	Indicator for appropriate range of desired closed staple height.	Same
	Safety Release for preventing from mis-firing.	Same
Outsider Diameter	32, 34 mm	Same
Cutting Diameter	23, 25 mm	Same
Number of Staples	32	Same
Closed Staples Height	1.9 mm	Similar
Closed Staples Form		Same
Hardness (Circular knife)	≧380HV0.2	Same
Pressure Resistance after Suturing	≥3.6kPa	Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Similar
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

Difference in Closed Staples Height and Sterilization between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Disposable Hemorrhoidal Stapler, is determined to be Substantially Equivalent (SE) to the predicate device, Procedure Sets for Prolapse and Hemorrhoids (K120179), in respect of safety and effectiveness.

Table 3-4 Disposable Endoscopic Linear Cutter Staplers and Reloads

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The Disposable Endoscopic Linear Cutter Staplers and Reloads have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.	Same
Operation Principle	Manual	Same
Cutting Mechanism	Linear	Same
Safety Mechanism	Green button for preventing from mis-firing.	Same
Suture Length	30, 45, 60 mm	Same
Cutting Length	26, 41, 58 mm	Similar
Closed Staples Height	1.5, 1.9 mm	Similar
Closed Staples Form		Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Similar
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

Difference in Cutting Length, Closed Staples Height and Sterilization between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Disposable Endoscopic Linear Cutter Staplers and Reloads, is determined to be Substantially Equivalent (SE) to the predicate device, Endoscopic Linear Cutting Staplers with Single Use Loading Units (K120179), in respect of safety and effectiveness.

Table 3-5 Disposable Linear Cutter Staplers and Reloads

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The Disposable Linear Cutter Staplers and Reloads have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the creation of anastomoses.	Same
Operation Principle	Manual	Same
Cutting Mechanism	Linear	Same
Safety Mechanism	Safety Release for preventing from mis-firing.	Same
Suture Length	56, 76, 81, 101 mm	Similar
Cutting Length	55, 75, 80, 100 mm	Similar
Number of Staples	32, 38, 42, 52	Similar
Closed Staples Height	1.5, 1.8 mm	Similar
Closed Staples Form		Same
Knife Hardness	≧380HV0.2	Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Similar
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

Difference in Suture Length, Cutting Length, Number of Staples, Closed Staples Height and Sterilization between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Disposable Linear Cutter Staplers and Reloads, is determined to be Substantially Equivalent (SE) to the predicate device, Linear Cutting Staplers with Single Use Loading Units (K120179), in respect of safety and effectiveness.

Table 3-6 Disposable Curved Cutter Stapler

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The Disposable Curved Cutter Stapler is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures.	Same
Operation Principle	Manual	Same
Cutting Mechanism	Circular Knife	Same
Safety Mechanism	Safety Release for preventing from mis-firing.	Same
Cutting Diameter	40 mm	Same
Row Number of Staples	4	Same
Closed Staples Height	1.9 mm	Similar
Closed Staples Form		Same
Knife Hardness	≧380HV0.2	Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Similar
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

Difference in Closed Staples Height and Sterilization between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Disposable Curved Cutter Stapler, is determined to be Substantially Equivalent (SE) to the predicate device, CONTOUR™ Curved Cutter Stapler and Reloads (K091322), in respect of safety and effectiveness.

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

Changzhou Sinolinks Medical Innovation Co., Ltd. July 5, 2013
% Mid-Link Consulting Co., Ltd.
Ms. Diana Hong
P.O. Box 120-119
Shanghai, 200120, China

Re: K131511
Trade/Device Name: Disposable Circular Stapler, Disposable Curved Cutter Stapler Disposable Linear Staplers and Reloads, Disposable Hemorrhoidal Stapler, Disposable Endoscopic Linear Cutter Staplers and Reloads, Disposable Linear Cutter Staplers and Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: May 21, 2013
Received: May 28, 2013

Dear Ms. Hong:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131511

Device Name: Disposable Circular Stapler / Disposable Linear Staplers and Reloads / Disposable Hemorrhoidal Stapler / Disposable Endoscopic Linear Cutter Staplers and Reloads / Disposable Linear Cutter Staplers and Reloads / Disposable Curved Cutter Stapler

Indications For Use:

The Disposable Circular Stapler has applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

The Disposable Linear Staplers and Reloads have application in the resection or transection of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.

The Disposable Hemorrhoidal Staple has application for general surgical treatment of hemorrhoids.

The Disposable Endoscopic Linear Cutter Staplers and Reloads have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

The Disposable Linear Cutter Staplers and Reloads have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the creation of anastomoses.

The Disposable Curved Cutter Stapler is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures.

Prescription Use ___X____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131511