Attachment II 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 21 CFR 807.92.

The assigned 510(k) Number: K120179

1. Date of Submission:12 JAN 2012

2. Sponsor

Reach Surgical, Inc.
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3. Submission Correspondent

Ms. Diana Hong &Mr. Lee Fu
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4. Proposed Device Identification

Proposed Device 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

Classification: II
Product Code: GDW
Regulation Number: 21 CFR 878.4750
Review Panel: General & Plastic Surgery

Intended Use Statement:

The Circular Staplers with Staples 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 Linear Staplers with Single Use Loading Units have application in the resection or transection of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.

The Procedure Sets for Prolapse and Hemorrhoids have application for general surgical treatment of hemorrhoids.

The Endoscopic Linear Cutting Staplers with Single Use Loading Units 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 Linear Cutting Staplers with Single Use Loading Units have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the creation of anastomoses.

5. Predicate Device Identification

510(k) Number: K090821
Product Name: Chex™ Single Use Curved Intraluminal Circular Stapler
Chex™ Single Use Reloadable Linear Stapler and Reloads
Chex™ Single Use Circular Stapler for Rectal Prolaps and Hemorrhoids
Chex™ Linear Cutter Disposable Reloadable Stapler
Manufacturer: Frankman International Limited

510(k) Number: K081146
Predicate Device Name: Echelon Endoscopic Linear Cutters (Articulating and Straight)
Manufacturer: Ethicon Endo-Surgery, LLC

6. Device Description

6.1 Circular Staplers with Staples

The proposed device, Circular Staplers with Staples, 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, so a circular anastomosis is created.

The staple is available in two specifications which are 4.8 mm and 3.5 mm to be used per different thickness of the tissue.

6.2 Linear Staplers with Single Use Loading Units

The proposed device, Linear Staplers with Single Use Loading Units (SULU) is a sterilized and disposable surgical instrument intended to beused 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 isavailable in 30 mm, 45 mm, 60 mm and 90 mm staple line length for use in various applications. Three staple sizes (2.5mm, 3.5 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.

6.3 Procedure Sets for Prolapse and Hemorrhoids

The proposed device, Procedure Sets for Prolapse and Hemorrhoids 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 Endoscopic Linear Cutting Staplers with Single Use Loading Units

The proposed device, Endoscopic Linear Cutting Staplers with Single Use Loading Units (SULU)is a sterilized and disposable surgical instrument, which has 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.

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 2.0 mm, 2.5 mm, 3.5 mm, 4.0 mm or 4.8 mm SULU.

The Endoscopic Linear Cutting Staplers are available in two kinds, which are Articulating and Straight. In addition, the Single Use Loading Units are also available in Articulating and Straight types. The Articulating Staplers could adjust the direction of the Single Use Loading Units (SULU) within a specified range if used together with Articulating SULU. The Articulating Staplers could also be used together with straight SULU without articulating features. The Straight stapler could only be used together with straight SULU.

When using the Endoscopic Linear Cutting Staplers with the 2.0, 2.5, 3.5 and 4.0 SULU, a 12 mm or larger trocar sleeve with a converter should be used. When using the Endoscopic Linear Cutting Staplers with the 4.8 SULU, a 15 mm trocar sleeve should be used. Endoscopic Linear Cutting Staplers may be reloaded and fired no more than 25 times in a single procedure. Each instrument can accommodate the following SULU specifications: 30-2.0, 30-2.5, 30-3.5, 45-2.0, 45-2.5, 45-3.5, 45-4.0, 45-4.8,60-2.5, 60-3.5, 60-4.0, 60-4.8.

6.5 Linear Cutting Staplers with Single Use Loading Units

The proposed device, Linear Cutting Staplers with Single Use Loading Units(SULU)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 Linear Cutting Staplers and SULU are available in 60 mm, 80 mm, and 100 mm lengths. SULU are available in two staple sizes to accommodate various tissue thicknesses: 3.8 mm and 4.8 mm.

7. Non-Clinical Test Conclusion

Bench 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: Package Integrity Testing, Physical Performance Testing, Sterilization Validation and Endotoxin Testing.

8. Substantially Equivalent Conclusion

The proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Reach Surgical, Inc
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Ms. Diana Hong
P.O. Box 237-023
Shanghai, China 200237

MAY 23 2012

Re: K120179
Trade/Device Name: Reach™ Surgical Staplers
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: April 17, 2012
Received: April 26, 2012

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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment I Indications for Use

510(k) Number: K120179

Device Name: Circular Staplers with Staples

Indications for Use:

The Circular Staplers with Staples 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.

☒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 ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120179

Indications for Use

510(k) Number: K120179

Device Name: Linear Staplers with Single Use Loading Units

Indications for Use:

The Linear Staplers with Single Use Loading Units have application in the resection or transection of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120179

Indications for Use

510(k) Number: K120179

Device Name: Procedure Sets for Prolapse and Hemorrhoids

Indications for Use:

The Procedure Sets for Prolapse and Hemorrhoids have application for general surgical treatment of hemorrhoids.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause MPH

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120179

Indications for Use

510(k) Number: K120179

Device Name: Endoscopic Linear Cutting Staplers with Single Use Loading Units

Indications for Use:

The Endoscopic Linear Cutting Staplers with Single Use Loading Units 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.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Division of Surgical, Orthopedic,
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510(k) Number K120179

Indications for Use

510(k) Number: K120179

Device Name: Linear Cutting Staplers with Single Use Loading Units

Indications for Use:

The Linear Cutting Staplers with Single Use Loading Units have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the creation of anastomoses.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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