

Section 3 510(k) Summary

JUL 25 2014

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: _____

1. Submission Date: 05/08/2014
2. Sponsor Identification

Touchstone International Medical Science Co., Ltd.
21A Science Plaza, International Science Park,
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Establishment Registration Number:

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3. Proposed Device Identification

3.1 Proposed Device for LS Series

3.1.1 Proposed Device Name: LS Series Linear Stapler and Reloads

3.1.2 Proposed Device Common Name: Stapler

3.1.3 Regulatory Information

Classification Name: staple, implantable

Classification: II

Product Code: GDW

Regulation Number: 21 CFR 878.4750

Review Panel: General & Plastic Surgery

3.1.4 Intended Use Statement

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

3.1.5 Device Description

The proposed device, LS Series Linear Stapler 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. It is available in 30 mm, 45 mm, 50 mm, 60 mm and 90 mm staple line length for use in various applications. Three staple sizes (2.5 mm, 3.5 mm, and 4.8 mm) are available to accommodate various tissue thicknesses. Each stapler could be reloaded no more than 11 times for total 12 firings.

It has two configurations: (1) LS serials are staplers, and (2) LSC serials are Reloads. Each of them has various specifications.

3.2 Proposed Device for CLC Series

3.2.1 Proposed Device Name: CLC Series Curved Linear Cutter and Reloads

3.2.2 Proposed Device Common Name: Stapler

3.2.3 Regulatory Information

Classification Name: staple, implantable

Classification: II

Product Code: GDW

Regulation Number: 21 CFR 878.4750

Review Panel: General & Plastic Surgery

3.2.4 Intended Use Statement

The CLC Series Curved Linear Cutter and Reloads 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.

3.2.5 Device Description

The proposed device, CLC Series Curved Linear Cutter and Reloads are sterilized and disposable surgical instrument, which has application in multiple open or minimally invasive general (gastrointestinal and skeletal muscle), gynecologic, urologic, and thoracic surgical procedures. It 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. It is available in 37mm and 43mm lengths. Two staple sizes (3.8 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.

It has two configurations: (1) CLC serials are staplers, and (2) CLCC serials are reloads. Each of them has various specifications.

3.3 Proposed Device for LC Series

3.3.1 Proposed Device Name: LC Series Linear Cutter and Reloads

3.3.2 Proposed Device Common Name: Stapler

3.3.3 Regulatory Information

Classification Name: staple, implantable

Classification: II

Product Code: GDW

Regulation Number: 21 CFR 878.4750

Review Panel: General & Plastic Surgery

3.3.4 Intended Use Statement

The LC Series Linear Cutter and Reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and the creation of anastomoses.

3.3.5 Device Description

The proposed device, LC Series Linear Cutter Stapler and Reloads are sterilized and disposable surgical instrument, which has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, 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. It is available in 60 mm, 80 mm and 100 mm lengths. Three staple sizes (3.8 mm, 4.2mm and 4.5 mm) are available to accommodate various tissue thicknesses. Each stapler could be reloaded no more than 11 times for total 12 firings.

It has two configurations: (1) LC serials are staplers, and (2) LCC serials are reloads. Each of them has various specifications.

3.4 Proposed Device for ELC Series

3.4.1 Proposed Device Name: ELC Series Endoscopic Linear Cutter and Single Use Loading Unit

3.4.2 Proposed Device Common Name: Stapler

3.4.3 Regulatory Information

Classification Name: staple, implantable

Classification: II

Product Code: GDW

Regulation Number: 21 CFR 878.4750

Review Panel: General & Plastic Surgery

3.4.4 Intended Use Statement

The ELC Series Endoscopic Linear Cutter and Single Use Loading Unit have applications in general, 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.

3.4.5 Device Description

The proposed device, ELC Series Endoscopic Linear Cutter and Single Use Loading Unit are 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. Five staple sizes (2.0mm, 2.5mm, 3.5mm, 4.0mm, and 4.8mm) are available to accommodate various tissue thicknesses. Each cartridge could be reloaded no more than 7 times for total 8 firings. It can be adapted for all of the reload sizes available.

It has two configurations: (1) ELC-G and ELC-T serials are staplers, and (2) MG and RG serials are cartridges. Each of them has various specifications.

4. Predicate Device Identification

4.1 Predicate Device for Disposable Linear Staplers and Reloads

510(k) Number: K131511

Product Name: Disposable Linear Staplers and Reloads

Manufacturer: Changzhou Sinolinks Medical Innovation Co., Ltd.

4.2 Predicate Device for Disposable Curved Cutter Stapler

510(k) Number: K131511

Product Name: Disposable Curved Cutter Stapler

Manufacturer: Changzhou Sinolinks Medical Innovation Co., Ltd.

4.3 Predicate Device for Disposable Linear Cutter Staplers and Reloads

510(k) Number: K131511

Product Name: Disposable Linear Cutter Staplers and Reloads

Manufacturer: Changzhou Sinolinks Medical Innovation Co., Ltd.

4.4 Predicate Device for Endoscopic Linear Cutting Staplers with Single Use Loading Units

510(k) Number: K120179

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

Manufacturer: Reach Surgical, Inc.

5. 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 dye penetration tests and seal strength test.

Shelf Life

6. 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 LS Series Linear Stapler and Reloads

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The LS Series Linear Stapler 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, 50, 60, 90 mm	Similar
Number of Staples	13, 19, 21, 23, 25, 39	Similar
Closed Staple Height	1.0, 1.5, 2.0 mm	Similar
Closed Staple Form		Same
Pressure Resistance after Suturing	≥3.6kPa	Same
Staple Material	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10 ⁻⁶	Same
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, Number of Staples, Closed Staple Height. Between the proposed and the 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, LS Series Linear Stapler and Reloads, is determined to be Substantially Equivalent (SE) to the predicate device, Disposable Linear Staplers and Reloads (K131511), in respect of safety and effectiveness.

Table 3-2 CLC Series Curved Linear Cutter and Reloads

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The CLC Series Curved Linear Cutter and Reloads 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	Curved Knife	Same
Safety Mechanism	Safety Release for preventing from mis-firing.	Same
Cutting Line	37, 43 mm	Similar
Row Number of Staple	4	Same
Closed Staple Height	1.5, 2.0 mm	Similar
Closed Staple Form		Same
Hardness (Circular knife)	$\geq 380\text{HV}_{0.2}$	Same
Pressure Resistance after Suturing	$\geq 3.6\text{kPa}$	Same
Staple Material	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Same
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

Difference in Cutting Line, Closed Staples Height. 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, CLC Series Curved Linear Cutter and Reloads, is determined to be Substantially Equivalent (SE) to the predicate device, Disposable Curved Cutter Stapler(K131511), in respect of safety and effectiveness.

Table 3-3 LC Series Linear Cutter and Reloads

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The LC Series Linear Cutter and Reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and the creation of anastomoses.	Same
Operation Principle	Manual	Same
Cutting Mechanism	Linear Knife	Same
Safety Mechanism	Safety Release for preventing from mis-firing.	Same
Suture Length	60, 80, 100 mm	Similar
Cutting Length	54, 74, 94 mm	Similar
Number of Staple	64, 84, 104	Similar
Closed Staple Height	1.5, 1.8, 2.0 mm	Similar
Closed Staple Form		Same
Hardness (Circular knife)	≥ 380HV _{0.2}	Same
Pressure Resistance after Suturing	≥ 3.6kPa	Same
Staple Material	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10 ⁻⁶	Same
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 Staple, Closed Staple Height. 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, LC Series Linear Cutter and Reloads, is determined to be Substantially Equivalent (SE) to the predicate device, Disposable Linear Cutter Staplers and Reloads(K131511), in respect of safety and effectiveness.

Table 3-4 ELC Series Endoscopic Linear Cutter and Single Use Loading Unit

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The ELC Series Endoscopic Linear Cutter and Single Use Loading Unit have applications in general, 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.	Same
Operation Principle	Manual	Same
Cutting Mechanism	Linear Knife	Same
Safety Mechanism	Green button for preventing from mis-firing	Same
Suture Length	30, 45, 60 mm	Same
Cutting Length	26, 41, 56 mm	Same
Closed Staple Height	0.75, 1.0, 1.5, 1.7, 2.0 mm	Same
Closed Staple Form		Same
Hardness (Circular knife)	$\geq 380\text{HV}_{0.2}$	Same
Pressure Resistance after Suturing	$\geq 3.6\text{kPa}$	Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Same
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

The proposed device, ELC Series Endoscopic Linear Cutter and Single Use Loading Unit, 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.



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

July 25, 2014

Touchstone International Medical Science Company, Ltd
Mr. Jo Qiao
Management Representative
21A Science Plaza, International Science Park
No. 1355 Jinjihu Avenue
Suzhou, 215021 P.R. CHINA

Re: K141367
Trade/Device Name: LS Series Linear Stapler and Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: May 26, 2014
Received: May 28, 2014

Dear Mr. Qiao:

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)

K141367

Device Name

LS Series Linear Stapler and Reloads

Indications for Use (Describe)

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

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)

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

Peter  Hudson -S

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Indications for Use

510(k) Number (if known)

K141367

Device Name

CLC Series Curved Linear Cutter and Reloads

Indications for Use (Describe)

The CLC Series Curved Linear Cutter and Reloads 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.

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)

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Indications for Use

510(k) Number (if known)

K141367

Device Name

LC Series Linear Cutter and Reloads

Indications for Use (Describe)

The LC Series Linear Cutter and Reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and the creation of anastomoses.

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)

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Indications for Use

510(k) Number (if known)

K14367

Device Name

ELC Series Endoscopic Linear Cutter and Single Use Loading Unit

Indications for Use (Describe)

The ELC Series Endoscopic Linear Cutter and Single Use Loading Unit have applications in general, 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.

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)

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