DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 14, 2017

Golden Stapler Surgical Co., Ltd.
% Ms. Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China

Re: K162707
Trade/Device Name: Single Use Circular Stapler, Single Use Hemorrhoidal Circular Stapler, Single Patient Use Linear Stapler And Reload, Single Patient Use Linear Cutter And Reload, Single Patient Use Endo Cutter And Reload, Single Patient Use Transverse Cutter And Reload
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: June 15, 2017
Received: June 19, 2017

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 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162707

Device Name
Single Use Circular Stapler, Single Use Hemorrhoidal Circular Stapler, Single Patient Use Linear Stapler and Reload, Single Patient Use Linear Cutter and Reload, Single Patient Use Endo Cutter and Reload, Single Patient Use Transverse Cutter and Reload

Indications for Use *(Describe)*
The Single Use Circular Stapler has application throughout the alimentary tract for end to end, end to side and side to side anastomoses.

The Single Patient Use Endo Cutter and Reload is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. It can be used with tissue buttressing materials.

The Single Patient Use Linear Cutter and Reload have application in gastrointestinal, gynecologic, thoracic, and pediatric surgery for transection, resection, and/or creation of anastomoses and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

The Single Patient Use Linear Stapler and Reload has applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection or transection of tissue and creation of anastomosis, including occlusion of the left atrial appendage in open procedures. They may be used for transection and resection of pancreas.

The Single Use Hemorrhodial Circular Stapler has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

The Single Patient Use Transverse Cutter and Reload 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 stapling), 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Exhibit #2 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K162707

1. Date of Preparation: 07/12/2017

2. Sponsor Identification

Golden Stapler Surgical Co., Ltd.
Building 7A, Jiangsu Wujin Sci-Tech Pioneer Park, 256, Mid Mingxin Road, Hutang Town, Wujin District, Changzhou, Jiangsu Province, China

Establishment Registration Number: Not yet registered

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Single Use Circular Stapler
Single Use Hemorrhoidal Circular Stapler
Single Patient Use Linear Stapler and Reload
Single Patient Use Linear Cutter and Reload
Single Patient Use Endo Cutter and Reload
Single Patient Use Transverse Cutter and Reload

Common Name: Stapler and Reload

Regulatory Information
Classification Name: Staple, Implantable
Classification: II;
Product Code: GDW
Subsequent Product Code: GAG
Regulation Number: 21CFR 878.4750
Review Panel: General& Plastic Surgery

Intended Use Statement:

The Single Use Circular Stapler has application throughout the alimentary tract for end to end, end to side and side to side anastomoses.

The Single Patient Use Endo Cutter and Reload is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. It can be used with tissue buttressing materials.

The Single Patient Use Linear Cutter and Reload have application in gastrointestinal, gynecologic, thoracic, and pediatric surgery for transection, resection, and/or creation of anastomoses and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

The Single Patient Use Linear Stapler and Reload has applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection or transection of tissue and creation of anastomosis, including occlusion of the left atrial appendage in open procedures. They may be used for transection and resection of pancreas.

The Single Use Hemorrhoidal Circular Stapler has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

The Single Patient Use Transverse Cutter and Reload 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 stapling), gynecologic, urologic, and thoracic surgical procedures.

Device Description

The Single Patient Use Transverse Cutter and Reload places four staggered curved row of titanium staples on the tissue upon activation, and cut the tissue between staple lines. The device is available in 40mm length with reload in 3.8mm and 4.5mm staple size. The device may be reloaded and fired up to 5 times in a single procedure.

Single Use Circular stapler 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 resect by the circular knife, and then a circular anastomosis is created. The stapler are available in 21mm, 23mm, 26mm, 29mm, 32mm and 34mm six specifications. The staple sizes are 4.8mm and 5.5mm.

Single Patient Use Endo Cutter and Reload places two, triple-staggered rows of titanium staples and simultaneously divides the tissue from central line. The devices are available in 30mm, 45mm and 60mm three lengths. Reloads are available in five staple sizes to accommodate various tissue thicknesses: 2.0mm, 2.5mm, 3.5mm, 3.8mm and 4.2mm. The device may be reloaded and fired up to 5 times in a single procedure.

Single Patient Use Linear Stapler and Reload places a double staggered row of titanium staples and is available in 30mm, 45mm, 60mm, and 90mm staple line length for use in various applications. Three staple sizes (2.5mm, 3.8mm and 4.5mm) are available to accommodate various tissue thicknesses. It may be reloaded and fired up to 4 times for a total 5 firing in a single procedure.

Single Patient Use Linear Cutter and Reload place two double staggered rows of titanium staples and simultaneously cut and divides tissue between the two double rows. The devices are available in 55mm, 60mm, 75mm, 80mm and 100mm lengths. Reloads are available in four staple sizes to accommodate various tissue thicknesses: 2.5mm, 3.8mm, 4.2mm and 4.5mm. It may be reloaded and fired up to 4 times for a total 5 firings in a single procedure.

Single Use Hemorrhoidal Circular Stapler 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 stapler are available in 30mm, 32mm, 34mm and 36mm four specifications. The staple size is 4.5mm. It cannot be reloaded.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K030411
Product Name: PROXIMATE® PPH Hemorrhoidal Circular Stapler and Accessories

Predicate Device 2
510(k) Number: K983536
Product Name: PROXIMATE® Curved and Straight Intraluminal Staplers

Predicate Device 3
510(k) Number: K020779
Product Name: ENDOPATH and PROXIMATE Linear Cutters and Staplers

Predicate Device 4
510(k) Number: K111825
Product Name: DST Series™ Staplers

Predicate Device 5
510(k) Number: K061156
Product Name: ENDOPATH Linear Cutters and Staplers

Predicate Device 6
510(k) Number: K062869
Product Name: CONTOUR™ Curved Cutter Stapler and Reloads

6. Identification of Reference Devices

Reference Device 1
510(k) Number: K080839
Product Name: Echelon™ Gray Cartridge-45mm

Reference Device 2
510(k) Number: K112056
Product Name: Echelon Endoscopic Linear Cutter Reload, Black

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. The test provided in this submission include:

Biocompatibility Test

Cytotoxicity Test	ISO 10993-5:2009
Skin Sensitization Test	ISO 10993-10:2010
Irritation Test	ISO 10993-10:2010

Performance tests performed on both subject device and predicate device include

Pressure Resistance Test in tissue (porcine intestine)
Closed Staple Height Test in tissue (porcine intestine)
Staple Formation Test in tissue (porcine intestine)
Force to Fire Stapler Test in tissue (porcine intestine)
Staple Line Integrity and Staple Formation in thick tissue (porcine stomach)

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics for Single Patient Use Transverse Cutter and Reload

Item	Proposed Device	Predicate Device 6 K062869
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Patient Use Transverse Cutter and Reload 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 stapling), gynecologic, urologic, and thoracic surgical procedures.	Same
Cutting Mechanism	Curved Knife	Same
Operation Principle	Manual	Same
Safety Mechanism	Reset Knob is used for preventing from mis-firing	Same
Closed staple height	1.5mm, 2.0mm	Same
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Unknown
Sterilization	Irradiation Sterilization	EO Sterilization
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 2 Comparison of Technology Characteristics for Single Use Circular Stapler

Item	Proposed Device	Predicate Device 2 K983536
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Use Circular Stapler has application throughout the alimentary tract for end to end, end to side and side to side anastomoses.	Same
Cutting Mechanism	Circular Knife	Same
Operation Principle	Manual	Same
Safety Mechanism	Insurance is used for preventing from mis-firing	Same
Closed staple height	1.0~2.5mm	Same
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Unknown
Sterilization	Irradiation Sterilization	EO Sterilization
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 3 Comparison of Technology Characteristics for Single Patient Use Endo Cutter and Reload

Item	Proposed Device	Predicate Device 5 K061156	Reference Device 1 K080839	Reference Device 2 K112056
Product Code	GDW	Same	Same	Same
Regulation Number	21 CFR 878.4750	Same	Same	Same
Intended Use	The Single Patient Use Endo Cutter and Reload is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures.	Same	Same	Same
Cutting Mechanism	Linear Knife	Same	Same	Same
Operation Principle	Manual	Same	Same	Same
Safety Mechanism	Green button for preventing from mis-firing	Same	Same	Same
Closed staple height	0.75, 1.0, 1.5, 1.8, 2.2mm	1.0, 1.5, 1.8, 2.0mm	0.75mm	2.3mm
Closed staple form				
Patient-contact material	Unalloyed Titanium Acrylonitrile-Butadiene-Styrene Stainless Steel	Unknown	Unknown	Unknown
Sterilization	Irradiation Sterilization	EO Sterilization	EO Sterilization	EO Sterilization
Endotoxin Limit	20 EU	Same	Same	Same
Labeling	Conforms with 21 CFR 801	Same	Same	Same

Table 4 Comparison of Technology Characteristics for Single Patient Use Linear Stapler and Reload

Item	Proposed Device	Predicate Device 4 K111825
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Patient Use Linear Stapler and Reload has applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection or transection of tissue and creation of anastomosis, including occlusion of the left atrial appendage in open procedures. They may be used for transection and resection of pancreas.	Same
Cutting Mechanism	N.A.	Same
Operation Principle	Manual	Same
Safety Mechanism	Safety release for preventing from mis-firing	Same
Closed staple height	1.0mm, 1.5mm, 2.0mm	Same
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Unknown
Sterilization	Irradiation Sterilization	EO Sterilization
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 5 Comparison of Technology Characteristics for Single Patient Use Linear Cutter and Reload

Item	Proposed Device	Predicate Device 3 K020779
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Patient Use Linear Cutter and Reload have application in gastrointestinal, gynecologic, thoracic, and pediatric surgery for transection, resection, and/or creation of anastomoses and can be used with staple line or tissue buttressing materials, such as bovine pericardium.	Same
Cutting Mechanism	Linear Knife	Same
Operation Principle	Manual	Same
Safety Mechanism	Safety release for preventing from mis-firing	Same
Closed staple height	1.0mm, 1.5mm, 1.8mm, 2.0mm	Same
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Unknown
Sterilization	Irradiation Sterilization	EO Sterilization
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 6 Comparison of Technology Characteristics for Single Use Hemorrhoidal Circular Stapler

Item	Proposed Device	Predicate Device 1 K030411
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Use Hemorrhoidal Circular Stapler has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.	Same
Cutting Mechanism	Circular Knife	Same
Operation Principle	Manual	Same
Safety Mechanism	Safety release for preventing from mis-firing	Same
Closed staple height	0.8~2.0mm	Same
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Unknown
Sterilization	Irradiation Sterilization	EO Sterilization
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

10. Substantially Equivalent (SE) Conclusion

Biocompatibility testing was performed on the proposed devices; including cytotoxicity, skin sensitization and irritation tests. The test results demonstrate that the device does not introduce any biocompatibility concerns. The proposed device is sterilized by radiation, a different method than the predicate, and sterility was established per ISO ISO11137. Therefore, testing demonstrates that the difference in patient contact material and sterilization method will not affect substantial equivalence.

The performance tests include pressure resistance test which is intended evaluate integrity of staple line, force to fire a stapler test which is intended to evaluate the force to fire a stapler, staple formation test which is intended to evaluate stapler formation characteristics, and closed staple height test which is intended evaluate whether the closed staple height can meet pre-defined criteria. The test results for both proposed device and predicate device was analyzed by statistical methods to ensure the sample size was appropriate to detect a meaningful difference between testing groups. The results show that there are no significant difference between proposed device and predicate device. Based on the comparison and performance test result analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.