DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 17, 2016

Changzhou Xin Neng Yuan Medical Stapler Co., Ltd.
c/o Ms. Diana Hong
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, China 100102

Re: K161905
Trade/Device Name: Disposable Circular Stapler for Hemorrhoids, Disposable Circular Stapler, Disposable Linear Stapler, Disposable Endoscopic Linear Cutter Stapler and Cartridge, Disposable Linear Cutter Stapler and Stapler Cartridge
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: October 19, 2015
Received: October 24, 2015

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" (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 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,

Jennifer R. Stevenson -A

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)*
K161905

Device Name
Disposable Linear Cutter Stapler and Stapler Cartridge, Disposable Circular Stapler, Disposable Endoscopic Linear Cutter Stapler and Cartridge, Disposable Linear Stapler, Disposable Circular Stapler for Hemorrhoids

Indications for Use *(Describe)*

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

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

The Disposable Endoscopic Linear Cutter Stapler and Cartridge 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 and biliary structures.

The Disposable Linear Cutter Stapler and Stapler Cartridge has application in abdominal, gynecological, thoracic and pediatric surgery transection, resection and the creation of anastomoses.

Disposable Circular Stapler for Hemorrhoids has application for general treatment of hemorrhoids

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.

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Exhibit #3 510(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: K161905

1. Date of Preparation: 10/19/2016

2. Sponsor Identification

Changzhou Xin Neng Yuan Medical Stapler Co., Ltd.
No.51 Shuishan Road, Zhonglou Economic Development Zone, Changzhou, 213023, China.

Establishment Registration Number: Not yet registered

Contact Person: Boping Ma
Position: General Manager
Tel: +86-519- 88830515
Fax: +86-519-86865852
Email: mbp129@126.com

3. Designated Submission Correspondent

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

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Disposable Linear Cutter Stapler and Stapler Cartridge
Disposable Circular Stapler
Disposable Endoscopic Linear Cutter Stapler and Cartridge
Disposable Linear Stapler
Disposable Circular Stapler for Hemorrhoids

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

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

The Disposable Endoscopic Linear Cutter Stapler and Cartridge 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 and biliary structures.

The Disposable Linear Cutter Stapler and Stapler Cartridge has application in abdominal, gynecological, thoracic and pediatric surgery transection, resection and the creation of anastomoses.

The Disposable Circular Stapler for Hemorrhoids has application for general treatment of hemorrhoids.

Device Description

The Disposable Linear Stapler 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. Two staple sizes

(3.8mm and 4.5mm) are available to accommodate various tissue thicknesses. It may be reloaded and fired up to 2 times for a total 3 firing in a single procedure.

Disposable Circular stapler place 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. It is available in 20, 22, 24, 26, 29, 32mm six specifications. Two staple sizes (4.7mm and 5.6mm) are available to accommodate various tissue thicknesses.

Disposable Endoscopic Linear Cutter Stapler and Cartridge places two double staggered rows of titanium staples and simultaneously cut and divides tissue between the two double rows. It is available in 30mm, 45mm, 60mm staple line length for use in various applications. Three staple sizes (2.5mm, 3.5mm and 4.8mm) are available to accommodate various tissue thicknesses. It may be reloaded and fired up to 2 times for a total 3 firing in a single procedure.

Disposable Linear Cutter Stapler and Stapler Cartridge places a two double staggered rows of titanium staples and simultaneously cut and divides tissue between the two double rows. The devices are available in 60mm, 80mm and 100mm lengths. Reloads are available in two staple sizes to accommodate various tissue thicknesses: 3.8mm and 4.5mm. It may be reloaded and fired up to 5 times for a total 6 firings in a single procedure.

Disposable Circular Stapler for Hemorrhoids 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 device is available in 34mm with 4.6mm staple.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K131511
Product Name: Disposable Circular Stapler
Disposable Linear Staplers and Reloads
Disposable Hemorrhoidal Stapler
Disposable Linear Cutter Staplers and Reloads

Predicate Device 2
510(k) Number: K120179
Product Name: Endoscopic Linear Cutting Staplers with Single Use Loading Units

6. 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 results demonstrated that the proposed device complies with the following standards:

- ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.
- ISO 10993-7: 2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- USP 38-NF 33 <85> Bacterial Endotoxins Tests
- ASTM F 88/F88M-09 Standard test method for seal strength of flexible barrier materials;
- ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages;

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics for Disposable Circular Stapler

Item	Proposed Device	Predicate Device 1 K131511
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Disposable Circular Stapler has applications throughout the alimentary tract for the creation of end-to-end, end-to-side anastomoses in both open and laparoscopic surgeries.	Same
Cutting Mechanism	Circular Knife	Same
Operation Principle	Manual	Same
Safety Mechanism	Insurance is used for preventing from mis-firing	Same
Closed staple height	2.0mm, 2.3mm	Similar
Closed staple form		
Patient-contact material	Unalloyed Titanium Acrylonitrile-Butadiene-Styrene Stainless Steel	Similar
Sterilization	EO Sterilization	Irradiation Sterilization
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 2 Comparison of Technology Characteristics for Disposable Endoscopic Linear Cutter Stapler and Cartridge

Item	Proposed Device	Predicate Device 2 K120719
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Disposable Endoscopic Linear Cutter Stapler and Cartridge 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 and biliary structures.	Same
Cutting Mechanism	Linear Knife	Same
Operation Principle	Manual	Same
Safety Mechanism	Safety button for preventing from mis-firing	Same
Closed staple height	1.0, 1.5, 1.8mm	similar
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Unknown
Sterilization	EO Sterilization	Same
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 3 Comparison of Technology Characteristics for Disposable Linear Stapler

Item	Proposed Device	Predicate Device 1 K131511
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Disposable Linear Stapler has application in the resection or transection of tissue for abdominal, gynecological, pediatric and thoracic surgical procedures.	Same
Cutting Mechanism	N.A.	Same
Operation Principle	Manual	Same
Safety Mechanism	Safety release for preventing from mis-firing	Same
Closed staple height	1.5mm, 2.0mm	similar
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	SE
Sterilization	EO Sterilization	Irradiation Sterilization
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 4 Comparison of Technology Characteristics for Disposable Linear Cutter Stapler and Stapler Cartridge

Item	Proposed Device	Predicate Device 1 K131511
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Disposable Linear Cutter Stapler and Stapler Cartridge has application in abdominal, gynecological, thoracic and pediatric surgery transection, resection and the creation of anastomoses.	Same
Cutting Mechanism	Linear Knife	Same
Operation Principle	Manual	Same
Safety Mechanism	Safety release for preventing from mis-firing	Same
Closed staple height	1.5mm, 1.7mm	similar
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Same
Sterilization	EO Sterilization	Irradiation Sterilization
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 5 Comparison of Technology Characteristics for Disposable Circular Stapler for Hemorrhoids

Item	Proposed Device	Predicate Device 1 K131511
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Disposable Circular Stapler for Hemorrhoids has application for general treatment of hemorrhoids.	Same
Cutting Mechanism	Circular Knife	Same
Operation Principle	Manual	Same
Safety Mechanism	Safety release for preventing from mis-firing	Same
Closed staple height	2.0mm	similar
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Same
Sterilization	EO Sterilization	Irradiation Sterilization
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.