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

December 5, 2016

Victor Medical Instruments Co., Ltd.
℅ Ms. Diana Hong
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, China 200120

Re: K161757
Trade/Device Name: Single Use Curved Cutters, Single Use Circular Staplers, Single Use Linear Cutters And Reloads, Single Use Endoscopic Linear Cutters And Reloads, Single Use Hemorrhoidal Staplers, Single Use Linear Staplers And Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 31, 2016
Received: November 4, 2016

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)*
K161757

Device Name
Single Use Curved Cutters, Single Use Circular Staplers, Single Use Linear Cutters and Reloads, Single Use Endoscopic Linear Cutters and Reloads, Single Use Hemorrhoidal Staplers, Single Use Linear Staplers and Reloads

Indications for Use *(Describe)*
The Single Use Endoscopic Linear Cutters and Reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

The Single Use Curved Cutters are 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.

The Single Use Circular staplers have application throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in abdominal or thoracic surgeries.

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

The Single Use Linear Cutters and Reloads have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection and the creation of anastomoses.

The Single Use Hemorrhoidal Staplers have 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: K161757

1. Date of Preparation: 12/05/2016

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Single Use Curved Cutters
Single Use Circular Staplers
Single Use Endoscopic Linear Cutters and Reloads
Single Use Linear Staplers and Reloads
Single Use Linear Cutters and Reloads
Single Use Hemorrhoidal Staplers
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

Indication for Use:

The Single Use Endoscopic Linear Cutters and Reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.

The Single Use Curved Cutters are 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.

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

The Single Use Linear Cutters and Reloads have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection and the creation of anastomoses.

The Single Use Hemorrhoidal Staplers have application for general treatment of hemorrhoids.

Device Description

The Single Use Curved Cutters place 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 4.8mm staple size.

Single Use Circular staplers 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. The stapler are available in 25mm, 27mm and 33mm three specifications. The staple is available in two specifications which are 4.8mm, 5.2mm to be used per different thickness of the tissue.

Single Use Endoscopic Linear Cutters and Reloads place two, triple-staggered rows of progressive 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 three staple sizes to accommodate various tissue thicknesses: 2mm-3mm, 3mm-4mm, 4mm-5mm. The device may be reloaded and fired up to 8 times in a single procedure.

Single Use Linear Staplers and Reloads place a double staggered row of titanium staples and is available in 30mm, 45mm, 60mm and 100mm staple line length for use in various applications. Two staple sizes (3.5mm and 4.8mm) are available to accommodate various tissue thicknesses. It may be reloaded and fired up to 7 times for a total 8 firing in a single procedure.

Single Use Linear Cutters and Reloads place 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 4.8mm. It may be reloaded and fired up to 7 times for a total 8 firings in a single procedure.

Single Use Hemorrhoidal Staplers are 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 32mm, 34mm two specifications. The staple size is 4.0mm. It cannot be reloaded.

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
Disposable Curved Cutter Stapler

Predicate Device 2
510(k) Number: K111825
Product Name: Endo GIA™ Staplers

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 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity.
- 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;
- ISO 11137-2: 2013 Sterilization of health care products -Radiation- Part 2: Establishing the sterilization dose

Bench test was conducted on swine stomach and intestine tissue for both proposed device and predicate device to determine substantially equivalence. The bench tests include following tests

- Pressure Resistance Test
- Closed Staple Height Test
- Staple Formation Test
- Force Required to Fire Stapler Test

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics for Single Use Curved Cutters

Item	Proposed Device	Predicate Device 1 K131511
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Use Curved Cutters are 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
Cutting Mechanism	Curved Knife	Same
Operation Principle	Manual	Same
Safety Mechanism	Reset Knob is used for preventing from mis-firing	Same
Closed staple height	2.0mm	1.9mm
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Same
Sterilization	Irradiation Sterilization	Same
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 2 Comparison of Technology Characteristics for Single Use Circular Staplers

Item	Proposed Device	Predicate Device 1 K131511
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Use Circular staplers have application throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in abdominal or thoracic 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, 2.2mm	Same
Closed staple form		
Patient-contact material	Unalloyed Titanium Acrylonitrile-Butadiene-Styrene Stainless Steel	Similar
Sterilization	Irradiation Sterilization	Same
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 3 Comparison of Technology Characteristics for Single Use Endoscopic Linear Cutters and Reloads

Item	Proposed Device	Predicate Device 2 K111825
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Use Endoscopic Linear Cutters and Reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.	Same
Cutting Mechanism	Linear Knife	Same
Operation Principle	Manual	Same
Safety Mechanism	Green button for preventing from mis-firing	Same
Closed staple height	0.8-1.5mm, 1.5-2.25mm, 2.25-3.0mm	Same
Closed staple form		
Patient-contact material	Unalloyed Titanium Acrylonitrile-Butadiene-Styrene Stainless Steel	Unknown
Sterilization	Irradiation Sterilization	Unknown
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 4 Comparison of Technology Characteristics for Single Use Linear Staplers and Reloads

Item	Proposed Device	Predicate Device 1 K131511
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Use Linear Staplers and Reloads have 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	1.5mm, 1.8mm
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Same
Sterilization	Irradiation Sterilization	Same
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 5 Comparison of Technology Characteristics for Single Use Linear Cutters and Reloads

Item	Proposed Device	Predicate Device 1 K131511
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Use Linear Cutters and Reloads have 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, 2.0mm	1.5mm, 1.8mm
Closed staple form		
Patient-contact material	Unalloyed Titanium Polycarbonate Stainless Steel	Same
Sterilization	Irradiation Sterilization	Same
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Same

Table 6 Comparison of Technology Characteristics for Single Use Hemorrhoidal Cutters

Item	Proposed Device	Predicate Device 1 K131511
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Intended Use	The Single Use Hemorrhoidal Staplers have 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	1.9mm
Closed staple form		
Patient-contact material	Unalloyed Titanium Acrylonitrile-Butadiene-Styrene Stainless Steel	Same
Sterilization	Irradiation Sterilization	Same
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.