DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 19, 2017

Standard Bariatrics
Ms. Alison Sathe
VP of Regulatory Affairs
4362 Glendale Milford Rd.
Cincinnati, Ohio 45242

Re: K170379
Trade/Device Name: Disposable Standard Clamp
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 1, 2017
Received: February 7, 2017

Dear Ms. Sathe:

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,

Jennifer R. Stevenson -S3

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)*
K170379

Device Name
Standard Clamp, Disposable

Indications for Use *(Describe)*
The Standard Clamp, Disposable is indicated for use in laparoscopic procedures to grasp, clamp, and manipulate soft tissues.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

I. SUBMITTER

Standard Bariatrics
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Cincinnati, OH 45242 USA

Phone: 513-30407971
Email: alison@standardbariatrics.com

Contact Person: Alison Sathe
Date Prepared: Feb. 1, 2017

II. DEVICE

Name of Device: Standard Clamp, Disposable
Common or Usual Name: Laparoscopic Surgical Instrument
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: II
Product Code: GCJ

III. PREDICATE DEVICE

Standard Bariatrics Standard Clamp, K161720
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Standard Clamp, Disposable is a disposable non-energized, hand held surgical instrument designed for use in laparoscopic procedures to clamp long planes of soft tissue such as the stomach. The Standard Clamp, Disposable is provided sterile (gamma). There are no accessories provided with the device. The instrument is comprised of three main sections: handle, shaft, and end effector. The handle is a pistol grip with a trigger and release button which are manually activated in order to open and close the end effector. The shaft is sized to fit a standard 12 mm trocar. The end effector of the clamp is comprised of an upper and lower jaw that close to grasp and hold tissue. The environment of use is in a hospital during laparoscopic surgical procedures.

V. INDICATIONS FOR USE

The Standard Clamp, Disposable is indicated for use in laparoscopic procedures to grasp, clamp, and manipulate soft tissues.

VI. INTENDED USE

The Standard Clamp, Disposable is intended to be used by a surgeon on a single patient during a single laparoscopic surgery under normal operating conditions. The Standard Clamp, Disposable is intended to

be inserted into the peritoneal cavity through a 12mm trocar and used in up to six cycles of opening and closure to grasp, clamp and manipulate long, 1.2 to 4.5mm thick, planes of soft tissues such as the stomach. The Standard Clamp, Disposable is not intended for direct contact with the cardiovascular system, lymphatic system or cerebrospinal fluid. The Standard Clamp, Disposable can be used while a surgeon uses devices such as a stapler adjacent to tissue that is clamped with the Standard Clamp, Disposable, e.g., to help guide endoscopic staplers during resection of tissue such as in sleeve gastrectomy.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: Technological Characteristics

Product	Standard Clamp, Disposable (proposed)	Standard Clamp, Reusable (161720)
Disposable/Reusable	Disposable	Reusable
Materials	End Effector: aluminum Shaft: stainless steel Handle: polycarbonate	End Effector: stainless steel Shaft: stainless steel Handle: stainless steel
Overall Length	26.3 inches (66.8 cm)	25.4 inches (64.5 cm)
End Effector Length	10.6 inches (27 cm)	10.6 inches (27 cm)
End Effector Width	0.47 inches (12 mm)	0.47 inches (12 mm)
Shaft Width	0.39 inches (10 mm)	0.39 Inches (10 mm)
Weight	0.5 lbs.	1.7 lbs.
Articulation	none	up to 55° from midline
End effector design	Aluminum jaws with non-piercing ridges to grasp tissue	Stainless steel jaws with non-piercing ridges to grasp tissue
End effector closure	Distal to proximal closure	Parallel closure
Handle	Pistol grip	Inline grip
Sterilization Method	Gamma Sterilization	Steam Sterilization
Anatomical Site Used	Various soft tissues accessible during laparoscopic procedures	Various soft tissues accessible during laparoscopic procedures
Types of procedures	Laparoscopic procedures	Laparoscopic procedures
Energy Delivered?	No	No
Compatible with 12 mm trocar?	Yes	Yes
Biocompatibility	Biocompatible for blood/bone/tissue contact for limited duration	Biocompatible for blood/bone/tissue contact for limited duration
Packaging	Tyvek pouch in cardboard box	Plastic pouch in cardboard box

VIII. PERFORMANCE DATA

Standard Clamp, Disposable performance bench testing was provided and demonstrated substantial equivalence to the predicate device. Clinical testing was not provided. Bench testing provided is described in Table 2.

Table 2: Bench Testing Summary

Testing	Purpose of Testing	Results	How Results Support Substantial Equivalence
Reliability Testing	Standard Clamp, Disposable devices were tested in simulated use conditions to demonstrate reliability of the device to perform 6 use cycles (i.e. opening and closure cycles) per the device specifications.	Testing was completed per the protocol without deviations. All samples met the requirements for trocar insertion, visual inspection and functional performance for each cycle. Standard Clamp, Disposable devices were cycled in simulated use cycles with zero failures.	The Standard Clamp, Disposable was tested to 95% reliability at 90% confidence, demonstrating the ability to perform for its intended use, similar to the predicate device.
Tissue Compression	Standard Clamp, Disposable devices were tested using excised porcine stomach to compare the clamping forces of the Standard Clamp, Disposable to the predicate device, reusable Standard Clamp.	Testing was completed per the protocol without deviations. Thirty (30) test runs demonstrated the Standard Clamp, Disposable compressed tissue with forces less than or equal to that of the Standard Clamp, Reusable.	Testing demonstrates that the clamping forces of the Standard Clamp, Disposable is less than or equal to that of the reusable Standard Clamp.
Tissue Slippage	Standard Clamp, Disposable devices were tested using excised porcine stomach to verify that the tissue will not slip from the jaws when a working load (i.e. a maximum load typically applied in surgical procedures) is applied to the tissue.	Testing was completed per the protocol without deviations. Thirty (30) test runs demonstrated that tissue did not slip from the Standard Clamp, Disposable jaws when a working load was applied to the tissue.	Testing demonstrates that tissue will not slip from the jaws of the Standard Clamp, Disposable 95% probability with 90% confidence. This demonstrates functionality substantially equivalent to the predicate device, reusable Standard Clamp.
Closure Strength	Standard Clamp, Disposable devices were tested to ensure the closure mechanism has a safety margin greater than or equivalent to 1.5. A safety margin of 1.5 ensures that the worst-case stress on the closure system will not exceed the strength of the device closure system (i.e. the device jaws will remain closed when placed in the closed position).	Testing was completed per the protocol without deviations. Ten (10)) test runs demonstrated that the closure mechanism demonstrated a safety margin of 11.6, exceeding the required safety margin	Testing demonstrates that the Standard Clamp, Disposable closure system is functional for device use. Testing demonstrates that the Standard Clamp, Disposable closure mechanism is substantially equivalent to that of the predicate.

CONCLUSIONS

The Standard Clamp, Disposable has the same indications, technological characteristics, principles of operation as its predicate device. There are no new issues of safety or effectiveness. Standard Clamp, Disposable is substantially equivalent to the predicate device.