September 27, 2018

Standard Bariatrics
Alison Sathe
Regulatory
4362 Glendale Milford Rd.
Cincinnati, Ohio 45242

Re: K181608
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: September 5, 2018
Received: September 5, 2018

Dear Alison 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181608

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. The Clamp is indicated for use in bariatric procedures such as sleeve gastrectomy as a guide, to clamp and manipulate flat tissue and organs, such as the stomach.

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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STANDARD BARIATRICS

# 510(K) Summary

## I. SUBMITTER

Standard Bariatrics
4362 Glendale Milford Road
Cincinnati, OH 45242 USA

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

Contact Person: Alison Sathe
Date Prepared: June 15, 2018

## 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, Disposable K170379
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. The Clamp is indicated for use in bariatric procedures such as sleeve gastrectomy as a guide, to clamp and manipulate flat tissue and organs, such as the stomach.

## 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 staplers during resection of tissue such as in sleeve gastrectomy.

## VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Standard Clamp, Disposable has the exact same technological characteristics as the predicate device.

*Table 1: Technological Characteristics*

| Product | Predicate Standard Clamp, Disposable (K170379) | Standard Clamp, Disposable (Subject) |
|---|---|---|
| Disposable/Reusable | Disposable | Same |
| Materials | End Effector: aluminum<br>Shaft: stainless steel<br>Handle: polycarbonate | Same |
| Overall Length | 26.3 inches (66.8 cm) | Same |
| End Effector Length | 10.6 inches (27 cm) | Same |
| End Effector Width | 0.47 inches (12 mm) | Same |
| Shaft Width | 0.39 inches (10 mm) | Same |
| Weight | 0.5 lbs. | Same |
| Articulation | none | Same |
| End effector design | Aluminum jaws with non-piercing ridges to grasp tissue | Same |
| End effector closure | Distal to proximal closure | Same |
| Handle | Pistol grip | Same |
| Sterilization Method | Gamma Sterilization | Same |
| Anatomical Site Used | Various soft tissues accessible during laparoscopic procedures | Same |
| Types of procedures | Laparoscopic procedures | Same |
| Energy Delivered? | No | Same |
| Compatible with 12 mm trocar? | Yes | Same |
| Biocompatibility | Biocompatible for blood/bone/tissue contact for limited duration | Same |
| Packaging | Tyvek pouch in cardboard box | Same |

VIII. PERFORMANCE DATA

Standard Clamp, Disposable performance bench testing was provided in K170379 and remains unchanged. Clinical data is provided in Section 020 of this submission. The data provided is a prospective, single-center, randomized controlled study performed independently of Standard Bariatrics including 30 subjects undergoing sleeve gastrectomy procedures. The study evaluated the number of staple cartridges used during cases with the Standard Clamp compared to those performed without the Standard Clamp. In addition to this quality metric, safety data was collected on all subjects.

After three-month follow-up, comparison of Standard Clamp to no clamp group revealed no significant difference in post-operative adverse event rate (9.5% vs. 5.6%, p = NS). No patients in the Standard clamp group required readmission or additional intervention. One patient was seen in the emergency department for syncope determined to be cardiac in nature and unrelated to the prior procedure. In the no clamp group, one patient was admitted approximately 1 week following surgery for intravenous hydration due to persistent nausea and emesis. Overall, there were no occurrences of postoperative leak, bleeding, or stricture formation noted in either group. The study demonstrates the safe use of the Standard Clamp in sleeve gastrectomy per its intended use.

IX. CONCLUSIONS

The Standard Clamp, Disposable has the same intended use, technological characteristics, and 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.