DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 24, 2016

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

Re: K161720
Trade/Device Name: Standard Clamp
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 31, 2016
Received: September 6, 2016

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 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)*
K161720

Device Name
Standard Clamp

Indications for Use *(Describe)*
The Standard Clamp 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.

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510(K) Summary

This 510(K) Summary of safety and effectiveness for the Standard Clamp is submitted in accordance with the requirements of the SMDA 1990 and FDA guidance concerning the organization and content of a 510(K) summary.

Applicant:	Standard Bariatrics
Address:	Standard Bariatrics 4362 Glendale Milford Road Cincinnati, OH 45242 USA
Contact Person:	Alison Sathe Director of Regulatory Standard Bariatrics
Telephone/Email/Fax:	513-304-7971 alison@standardbariatrics.com
Preparation Date:	June 16, 2016
Device Trade Name:	Standard Clamp
Common Name:	Laparoscopic Surgical Instrument
Classification Name:	Endoscope and accessories (GCJ, 21 CFR 876.1500)
Legally Marketed Predicate Device(s):	Standard Bariatrics Standard Clamp – K153358 Aesculap Inc. Manual Laparoscopic Instruments – K944467

Device Description:
The Standard Clamp is a reusable, non-energized, stainless steel surgical instrument designed for use in laparoscopic procedures to clamp long planes of soft tissue such as the stomach. The instrument is comprised of three main sections: handle, shaft, and end effector. The handle is an inline grip with two knobs which are manually rotated in order to manipulate 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 parallel in order to grasp tissue.

Intended Use:
The Standard Clamp is a hand held device used during laparoscopic surgery to clamp long planes of soft tissues. The device allows the surgeon to clamp and manipulate flat tissue and organs, such as the stomach. The clamp can also be used by the surgeon to help guide endoscopic staplers during resection of tissue.

Indication for Use:
The Standard Clamp is indicated for use in laparoscopic procedures to facilitate grasping, mobilization, and transection of tissue.

Technological Characteristics:
The Standard Clamp is a non-energized, manually articulated, laparoscopic clamp. The device is comprised of stainless steel and is validated for sterilization by steam autoclave. Two knobs on the device handle allow the user to adjust the angle of the end effector with respect to the shaft and open/close the jaws.

Table 1: Technological Characteristics

Product	Standard Clamp (proposed)	Standard Clamp (K153358)	Aesculap Manual Laparoscopic Instruments (K944467)
Type of Device	Reusable	Reusable	Reusable
Materials (end effector)	Stainless Steel	Stainless Steel	Stainless Steel
Length (Overall)	25.4 inches (64.5 cm)	25.4 inches (64.5 cm)	unknown
Length (end effector)	10.6 inches (27 cm)	10.6 inches (27 cm)	4 inches (10 cm)
Width of end effector	0.4 inches (1 cm)	0.4 inches (1 cm)	0.4 inches (1 cm)
Weight	1.7 lbs.	1.7 lbs.	1 lb.
Articulation Mechanism	Rotating knob on handle	Rotating knob on handle	Rotating knob on handle
Articulation	up to 55° from midline	up to 55° from midline	up to 45° from midline
End effector design	Stainless steel jaws with non-piercing ridges to grasp tissue	Stainless steel jaws with non-piercing ridges to grasp tissue	Stainless steel jaws without ridges to grasp tissue
End effector closure	Parallel closure	Parallel closure	Scissor-type closure
Handle	In-line grip	In-line grip	Pistol grip
Sterilization Method	Steam Sterilization	Steam Sterilization	Steam Sterilization
Flush Port?	Yes	Yes	Unknown
Anatomical Site Used	Various soft tissues accessible during laparoscopic procedures	Various soft tissues accessible during open procedures	Various soft tissues accessible during laparoscopic procedures
Types of procedures	Laparoscopic procedures	Open procedures	Laparoscopic procedures
Energy Delivered?	No	No	No

Compatible with 12 mm trocar?	Yes	Yes	Yes
Biocompatibility	Biocompatible for blood/bone/tissue contact for limited duration	Biocompatible for blood/bone/tissue contact for limited duration	Biocompatible for blood/bone/tissue contact for limited duration

Performance Data:
Pre-clinical evaluation of the device was performed to ensure the device may be used as designed. The Standard Clamp was used in a live anesthetized pig to evaluate the ability to clamp on tissue without damaging tissue as compared to other laparoscopic graspers and clamps. Clamps were placed on the porcine stomach laparoscopically. Tissue effects were observed *in vivo* during clamping and after release. After clamping, the stomach was resected and histology samples were analyzed for each clamp.

Testing demonstrated acceptable performance of the Standard Clamp. No damage to surrounding tissues were caused by any of the clamps. There histology demonstrated similar types of tissue effects between the three clamps. The data demonstrate conformance to the device specifications.

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