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

May 2, 2016

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

Re: K153358
Trade/Device Name: Standard Clamp
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument For General Use
Regulatory Class: Class I
Product Code: GDJ
Dated: March 27, 2016
Received: April 4, 2016

Dear Ms. 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. 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)*
K153358

Device Name
Standard Clamp

Indications for Use *(Describe)*
The Standard Clamp is indicated for use in open 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

This 510(K) Summary of safety and effectiveness for the Standard Clamp is submitted in accordance with 21 CFR 807.92.

Submitter Information	
Applicant Name	Standard Bariatrics
Address	Standard Bariatrics 4362 Glendale Milford Road Cincinnati, OH 45242 USA
Contact Person	Alison Sathe Regulatory, Standard Bariatrics
Telephone/Email/Fax	513-304-7971 alison@standardbariatrics.com
Preparation Date	December 7, 2015
Device Information	
Device Trade Name	Standard Clamp
Common Name	Manual Surgical Instrument
Classification Name	Manual surgical instrument for general use
Classification Panel	79 General and Plastic Surgery
Regulation	Class I per 32 CFR 878.4800, product code GDJ
Legally Marketed Predicate Device(s)	Doyen Atraumatic Bowel Clamp
Product Code	SCR25
Reason for 510(k)	New Device
Device Description	The Standard Clamp is a reusable, non-energized, stainless steel surgical instrument. 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 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 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 staplers during transection of tissue.
Indications for Use:	The Standard Clamp is indicated for use in open procedures to grasp, clamp, and manipulate soft tissues.

Technological Characteristics: The Standard Clamp is a non-energized, manually articulated, surgical 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. Technical specifications are as follows:

Product	Standard Clamp	Doyen Atraumatic Bowel Clamp
Type of Device	Reusable	Reusable
Materials (end effector)	Stainless Steel	Stainless Steel
Length	25.4 inches (64.5 cm)	9 inches
Weight	1.7 lbs.	unknown
Articulation Mechanism	Rotating knob on handle	none
Articulation	up to 55° from midline	Available in curved or straight configuration
End effector design	Stainless steel jaws with non-piercing ridges to grasp tissue	Stainless steel jaws with non-piercing ridges to grasp tissue
End effector closure	Parallel closure	Scissor-type closure
Handle	In-line grip	In-line grip
Sterilization Method	Steam Sterilization	Steam Sterilization
Flush Port	Yes	No
Anatomical Site Used	Various soft tissues	Various soft tissues
Energy Delivered	No	No
Biocompatibility	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 Standard Clamp was performed to ensure the device may be used as designed. The device ability to clamp the stomach was evaluated in vivo. Tissue effects from the Standard Clamp were compared to other surgical devices including surgical staplers, soft tissue clamps, and graspers in a histological assessment. The Standard Clamp demonstrated little or no tissue effect after being clamped on stomach for an extended period of time as observed under histology. The Standard Clamp exhibited less tissue damage compared to graspers and surgical staplers with the exception of the Doyen clamp which also demonstrated no damage to tissue. Testing demonstrates acceptable performance of the Standard Clamp, its ability to clamp the stomach, and non-traumatic tissue effect.

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.