STANDARD BARIATRICS™

510(K) Summary

I. SUBMITTER

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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 K181608

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. The current Standard Clamp, Disposable has a jaw length of 25 cm. This Special 510(k) is being filed to add a new shorter jaw length (22 cm) to accommodate patients with smaller abdomens.

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.

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. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Standard Clamp, Disposable has the same technological characteristics as the predicate device with the exception of jaw length.

Table 1: Technological Characteristics

Product	Predicate Standard Clamp, Disposable (product code SCD25) (K181608)	Standard Clamp, Disposable (product code SCD22) (Subject)
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.	Same
Disposable/Reusable	Disposable	Same
Materials	End Effector: aluminum Shaft: stainless steel Handle: polycarbonate	Same
Overall Length	26.3 inches (66.8 cm)	25.1 inches (63.8 cm)
End Effector Length	10.6 inches (27 cm)	9.4 inches (24 cm)
End Effector Clamping Length	9.8 inches (25 cm)	8.9 inches (22 cm)
End Effector Width	0.47 inches (12 mm)	Same
Shaft Width	0.39 inches (10 mm)	Same
Weight	0.5 lbs.	0.5 lbs.
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 a cardboard box	Tyvek covered tray in cardboard box

VII. PERFORMANCE DATA

Standard Clamp, Disposable performance bench testing was provided in K170379. Testing for the Standard Clamp, Disposable 22 cm is provided in Section 018 – Performance Testing - Bench of this submission to the same specifications as the Standard Clamp, Disposable 25 cm previously provided in K170379. The data demonstrates that the Standard Clamp, Disposable 22 cm meets the same specifications for clamping and slip force as the Standard Clamp, Disposable 25 cm. The packaging change has been validated and data is provided in Section 014 – Sterilization and Shelf Life.

VIII. CONCLUSIONS

The Standard Clamp, Disposable has the same intended use and principles of operation as its predicate device. The only difference in technological characteristics is the jaw being offered in a shorter length in order to accommodate varying anatomy. The Standard Clamp, Disposable 22 cm meets the same specifications as the previously cleared Standard Clamp, Disposable 25 cm. There are no new issues of safety or effectiveness. Standard Clamp, Disposable is substantially equivalent to the predicate device.