DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 7, 2016

Teleflex Medical
Ms. Holly Hallock
Senior Regulatory Affairs Specialists
Surgical Business Unit
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K161758
Trade/Device Name: Weck Auto Endo10 Automatic Endoscopic Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP, GDO
Dated: June 24, 2016
Received: June 27, 2016

Dear Ms. Hallock:

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,

David Krause -S

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)*
K161758

Device Name
Weck Auto Endo10 Automatic Endoscopic Clip Applier

Indications for Use *(Describe)*
Weck Auto Endo10 Hem-o-lok L automatic endoscopic ligating clip appliers are indicated for use as delivery devices for Hem-o-lok L non-absorbable polymer ligating clips. These appliers are designed for use with 10/11 mm cannulas.

Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated so that the clip completely encompasses the vessel or tissue structure.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY – K161758

Weck® Auto Endo10® Automatic Endoscopic Clip Applier

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 919-361-4071
Fax: 919-433-4996

B. Contact Person

Holly Hallock
Senior Regulatory Affairs Specialist

C. Date Prepared

August 30, 2016

D. Device Name

Trade Name:	Weck® Auto Endo10® Automatic Endoscopic Clip Applier
Model Number:	AE10LG
Common Name:	Implantable Clip
Classification Name:	Clip, Implantable
Product Code:	FZP
Regulation:	878.4300

E. Device Description

The Weck® Auto Endo10® Automatic Endoscopic Clip Applier is an automatic, endoscopic applier that is pre-loaded with twelve (12) Hem-o-lok large, non-absorbable polymer ligating clips. The applier is an ethylene oxide (EO) sterile, disposable device that is intended to be used by a surgeon or physician's assistant during laparoscopic procedures when ligation of vessels or tissue structures is necessary. The Auto Endo10 Automatic Endoscopic Applier employs a pistol grip handle which is housed in a body assembly. The applier is 49.37cm long with a working length of 35.2cm. The device is designed for use with a 10/11mm cannula and includes a knob to allow 360° rotation of the applier shaft for clip positioning using the index finger of the gripping hand.

F. Indications for Use

The following indications for use are identical to those of the predicate, with the exception that they reference the larger size slip and the larger corresponding cannulas. These variations are due to the fact that the proposed Auto Endo10 delivers pre-loaded large clips and the predicate delivers medium-large clips.

The Weck Auto Endo10 Hem-o-lok L automatic endoscopic ligating clip appliers are indicated for use as delivery devices for Hem-o-lok L non-absorbable polymer ligating clips. These appliers are designed for use with 10/11mm cannulas.

Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel to or tissue structure to be ligated so that the clip completely encompasses the vessel or tissue structure.

G. Contraindications

Hem-o-lok Ligating Clips are not intended for use as a contraceptive tubal occlusion device.

Hem-o-lok Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

H. Environmental Conditions

Hem-o-lok Ligating Clips are “MR Safe” and pose no known hazards in MR environments. This claim was cleared under K133202, December 30, 2013.

I. Substantial Equivalence

The proposed Auto Endo10 Automatic Endoscopic Applier is substantially equivalent to the predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Weck Auto Endo5 5mm Automatic Endoscopic 35cm Applier	Teleflex Medical	K152081	08/26/2015

J. Comparison To Predicate Devices

The proposed Auto Endo10 Automatic Endoscopic Applier has the same technology and functional characteristics as the predicate device.

This submission discusses a line extension to add an automatic applier intended to deliver large Hem-o-lok Ligating Clips through a 10mm shaft during laparoscopic procedures. This differs from the predicate in that the Auto Endo5 device delivers medium-large Hem-o-lok clips through a 5mm shaft.

Additional differences include the addition of a lock pin in the subject device for the purposes of reducing movement of preloaded clips during distribution and storage as well as insert-molding of the actuator for the purpose of maintaining the design intent while utilizing a larger shaft.

The subject device is pre-loaded with twelve (12) ligating clips, whereas the predicate houses fifteen (15); this is due to the larger size of the clips. Channel spring fingers have been added as internal components to the device to support the

larger size clips. Additionally, the larger size clips require a slight modification to the handle ratchet profile.

The rotation knob on the subject device is purple as opposed to green on the predicate device. Rotation knob color is consistent with the color-coding established for the Hem-o-lok Ligation family.

Lastly, the subject device's manufacturing location and sterilization facility have changed.

K. Materials

All patient contacting materials, including those with indirect patient contact, have been evaluated according to ISO 10993-1 and the FDA's Guidance Use of International Standard ISO 10993-1, dated June 16, 2016. All biocompatibility testing was successful.

L. Technological Characteristics

A comparison of the technological characteristics of the proposed Auto Endo10 Automatic Endoscopic Applier and the predicate has been performed. The results of this comparison demonstrate that the Auto Endo10 Automatic Endoscopic Applier is equivalent to the marketed predicate device.

M. Performance Data

Non-clinical performance testing has been conducted following product sterilization, environmental conditioning, and simulated distribution in order to support the line extension to add a large automatic applier. Benchtop testing for the Auto Endo10 Automatic Endoscopic Applier included visual inspection, device weighing, trocar compatibility, aperture check, clip retention, knob rotation, clip closure, and trigger force measurement.

Usability and design validation of the Auto Endo10 Automatic Endoscopic Applier in a porcine model was conducted to document that the clip applier performed to its intended use *in vivo*, the user was able to operate the system as intended, and the product conformed to user needs.

N. Nonclinical Tests

The following nonclinical tests have been conducted on the proposed Auto Endo10:

Test	Standard	Result
EO Sterilization Validation	ISO 11135:2014 ISO 10993-7:2008	Pass
Packaging Verification	ISO 11607-1:2006 (A1:2014) ISO 11607-2:2006 (A1:2014) ASTM D4169-14 ASTM F88/F88M-09 ASTM F2096-11	Pass

Shelf Life Testing (One Year)	ASTM F1980-07/(R)2011	Pass
Biocompatibility Testing	ISO 10993-1:2009	Pass
Benchtop Design Verification	N/A	Pass
Usability and Design Validation (Animal Lab)	AAMI/ANSI HE75:2009(R)2013 IEC 62366:2007(A1:2014)	Pass
Supplemental Validation (Hospital Setting)	N/A	Pass
Trocar Compatibility Testing	N/A	Pass

O. Conclusion

Based upon the performance and comparative test results, the proposed Auto Endo10 Automatic Endoscopic Applier is substantially equivalent in performance to the predicate device cleared to market via 510(k) K152081. The line extension discussed within this submission does not introduce any new issues of safety and effectiveness.