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

August 26, 2015

Teleflex Medical Incorporated
Ms. Ashlea Ricci
Senior Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K152081
Trade/Device Name: Weck Auto Endo5 5mm Automatic Endoscopic 35cm Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: July 24, 2015
Received: July 27, 2015

Dear Ms. Ricci:

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" (21CFR 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,

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)*

K152081

Device Name
Weck Auto Endo5, 5mm Automatic Endoscopic 35cm Applier

Indications for Use *(Describe)*
Weck Auto Endo5 Hem-o-lok ML automatic endoscopic ligating clip appliers are indicated for use as delivery devices for Hem-o-lok ML non-absorbable polymer ligating clips. These appliers are designed for use with 5/5.5mm 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Weck® Auto Endo5® 5mm Automatic Endoscopic 35cm 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

Ashlea Ricci, MSRS, RAC
Senior Regulatory Affairs Specialist

C. Date Prepared

August 5, 2015

D. Device Name

Trade Name:	Weck Auto Endo5 5mm Automatic Endoscopic 35cm Applier
Common Name:	Implantable Clip
Classification Name:	Clip, Implantable
Product Class:	Class 2
Product Code:	FZP
Regulation Number:	878.4300

E. Device Description

The Auto Endo5 5mm Automatic Endoscopic 35cm Applier is an automatic, endoscopic applier that is pre-loaded with fifteen (15) Hem-o-lok medium-large, non-absorbable polymer ligating clips. The applier is a 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 Endo5 5mm Automatic Endoscopic 35cm Applier employs a trigger 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 5/5.5mm 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 Weck Auto Endo5 Hem-o-lok ML automatic endoscopic ligating clip appliers are indicated for use as delivery devices for Hem-o-lok ML non-absorbable polymer ligating clips. These appliers are designed for use with 5/5.5mm 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 Endo5 5mm Automatic Endoscopic 35cm Applier is substantially equivalent to the predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Weck Auto Endo5 Hem-o-lok Ligating Clip Applier	Teleflex Medical	K142777	12/19/2014

J. Comparison To Predicate Devices

The proposed Auto Endo5 5mm Automatic Endoscopic 35cm Applier has the same technology and functional characteristics as the predicate device. The modifications proposed within this submission include extending the device’s working length by 5.5cm, a minor modification to the ratcheting mechanism to improve audible cues during use and a change in the color of the trigger from green to white.

K. Materials

All patient contacting materials, including those with indirect patient contact, are in compliance with ISO 10993-1.

L. Technological Characteristics

A comparison of the technological characteristics of the proposed Auto Endo5 5mm Automatic Endoscopic 35cm Applier and the predicate has been performed. The results of this comparison demonstrate that the Auto Endo5 5mm Automatic Endoscopic 35cm 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 a change to the device's working length and ratcheting mechanism.

Usability and design validation of the Auto Endo5 5mm Automatic Endoscopic 35cm 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. Conclusion

Based upon the performance and comparative test results, the proposed Auto Endo5 5mm Automatic Endoscopic 35cm Applier is substantially equivalent in performance to the predicate device cleared to market via 510(k) K142777. The modifications made to the Auto Endo5 5mm Automatic Endoscopic 35cm Applier do not introduce any new issues of safety and effectiveness.