April 28, 2023

Teleflex Medical
Hope West
Senior Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K230480
Trade/Device Name: Weck Auto Endo5 5mm Automatic Endoscopic 35cm Applier (AE05ML)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP, GDO
Dated: February 21, 2023
Received: February 22, 2023

Dear Hope West:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tajanay R. Ki -S

Digitally signed by Tajanay R. Ki -S
Date: 2023.04.28 17:06:11 -04'00'

for Deborah Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230480

Device Name
Weck Auto Endo5 5mm Automatic Endoscopic 35cm Applier (AE05ML)

Indications for Use *(Describe)*
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 or tissue structures to be ligated such 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.

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

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510(k) SUMMARY – K230480 – 28April2023

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: 919-544-8000
Fax: 919-433-4996

B. Contact Person

Hope West, RAC-Devices,
Sr. Regulatory Affairs Specialist

C. Date Prepared

February 21, 2023

D. Device Name

Trade Name:	Weck Auto Endo5® 5mm Automatic Endoscopic 35cm Applier
Common Name:	Implantable Clip
Classification Name:	Applier, Surgical, Clip Clip, Implantable
Product Code:	GDO, FZP

E. Predicate Device

The proposed Auto Endo5® 5mm Automatic Endoscopic 35cm Applier is substantially equivalent to the predicate device:

Predicate Device	Manufacturer	510(k) No.	Product Code	Date Cleared
Weck Auto Endo5® Hem-o-lok® Ligating Clip Applier	Teleflex Medical	K152081	FZP	08/26/2015

F. Comparison To Predicate Devices

The proposed Auto Endo5® 5mm Automatic Endoscopic 35cm Applier is substantially equivalent to the predicate device with respect to technology, intended use, indications, and functional characteristics. The modifications proposed within this submission are minor changes that align to the original device design intent and do not introduce any new issues of safety and effectiveness.

G. 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 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 49cm long with a working length of 35cm. 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.

H. 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.

I. Contraindications

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

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

J. Environmental Conditions

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

K. Materials

All patient contacting materials are equivalent to the predicate, including those with indirect patient contact, and are in compliance with ISO 10993-1 according to their nature and duration of contact.

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 device modifications and ensure the device performed equivalently to the predicate.

Usability and design validation of the Auto Endo5® 5mm Automatic Endoscopic 35cm Applier in a simulated use environment was conducted to document that 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) K152081. The modifications made to the Auto Endo5® 5mm Automatic Endoscopic 35cm Applier do not introduce any new issues of safety and effectiveness.