



January 12, 2024

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

Re: K232970

Trade/Device Name: Hem-o-lok® Ligating Clips
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: September 20, 2023
Received: September 21, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Julie A. Morabito -S

Julie Morabito, Ph.D.

Assistant Director

DHT4B: Division of Infection Control

and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K232970

Device Name

Hem-o-lok® Ligating Clips

Indications for Use (Describe)

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 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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K232970 510(k) SUMMARY

Hem-o-lok® Ligating Clips

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,
Pr. Regulatory Affairs Specialist

C. Date Prepared

10 January 2024

D. Device Name

Trade Name: Hem-o-lok® Ligating Clips
Common Name: Implantable Clip
Classification Name: Clip, Implantable
Product Code: FZP, 21 CFR 878.4300

E. Device Description

Hem-o-lok® Ligating Clips are single-use, non-active implantable devices designed for use in general surgical procedures that require vessel or tissue ligation. The clips are available in four sizes (Medium, Medium-Large, Large, Extra Large), allowing the end user to ligate a wide range of vessels and tissue structures. Hem-o-lok® Ligating Clips are manufactured from a non-absorbable acetyl polymer and are provided prepackaged in color-coded cartridges, which are provided as single-use, sterile devices.

Accessories to the Hem-o-lok® Ligating Clips include manual clip applicators and removers for use in both general open and endoscopic procedures. Both the applicators and removers are multiple use, non-sterile devices that require cleaning and sterilization prior to each use.

F. Indications for Use

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 such that the clip completely encompasses the vessel or tissue structure.

G. 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.

H. Environmental Conditions

Hem-o-lok® Ligating Clips are “MR Safe” and pose no known hazards in MR environments.

I. Substantial Equivalence

The proposed Hem-o-lok® Ligating Clips are substantially equivalent to the predicate device with respect to technology, intended use, indications and technological characteristics:

	New Submission	Predicate	Equivalence
510(k) Number	K232970	K133202	N/A
Device Name	Hem-o-lok® Ligating Clips	Hem-o-lok® Ligating Clips	Identical
Product Code	FZP	FZP	Identical
Regulation	878.4300	878.4300	Identical
Intended Use	Ligation of vessels and tissue structures		Identical
Indications for Use	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.		Identical
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.		Identical
Clip Size Offering	Medium, Medium-Large, Large, Extra-Large	Medium, Medium-Large, Large, Extra-Large	Identical
Clip Material	Acetyl Polymer	Acetyl Polymer	Equivalent
Clip Design	Hinged, bow-shape clip with bosses for clip retention within the appliers, and a locking mechanism	Hinged, bow-shape clip with bosses for clip retention within the appliers, and a locking mechanism	Identical
Cartridge Design	Easy Load with lateral springs	Easy Load with lateral springs	Identical
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Equivalent
Sterilization	Ethylene Oxide (EO); SAL 10 ⁻⁶	Ethylene Oxide (EO); SAL 10 ⁻⁶	Equivalent

J. Performance Data

Non-clinical performance testing, consisting of benchtop verification testing for clip latching, resistance to leakage, and clip removal, has been conducted following product sterilization, environmental conditioning, simulated distribution, and accelerated aging in order to ensure the device performed equivalently to the predicate.

The following biocompatibility endpoints were assessed per ISO 10993-1:

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Intracutaneous Reactivity per ISO 10993-10
- Systemic toxicity (acute) per ISO 10993-11
- Subchronic toxicity (subacute) per ISO 10993-11
- Implantation per ISO 10993-6
- Material Mediated Pyrogenicity per ISO 10993-11
- Chronic Toxicity per ISO 10993-11
- Genotoxicity per ISO 10993-3
- Carcinogenicity per ISO 10993-3
- Chemical Characterization per ISO 10993-18

K. Conclusion

Based upon the performance and comparative test results, the proposed Hem-o-lok® Ligating Clip (K232970) is substantially equivalent in performance to the predicate device cleared to market via 510(k) K133202. The proposed device does not introduce any new issues of safety and effectiveness.