July 03, 2025

Teleflex Medical
Hope West
Pr. Regulatory Affairs Specialist
3015 Carrington Mill Bld
Morrisville, North Carolina 27560

Re: K251054
Trade/Device Name: Hem-o-lok™ PurplePlus™ Large Polymer Ligating Clips
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: April 3, 2025
Received: April 4, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251054

Device Name
Hem-o-lok™ PurplePlus™ Large Polymer Ligating Clips

Indications for Use *(Describe)*
The Hem-o-lok™ PurplePlus™ Large Polymer Ligating Clips are intended for use in procedures involving the 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY - K251054

Hem-o-lok™ Purple*Plus*™ Large Polymer 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

15May2025

D. Device Name

Trade Name:	Hem-o-lok™ Purple*Plus*™ Large Polymer Ligating Clips
Common Name:	Implantable Clip
Classification Name:	Clip, Implantable
Product Code:	FZP, 21 CFR 878.4300

E. Device Description

Hem-o-lok™ Purple*Plus*™ Large Polymer 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 manufactured from a non-absorbable acetal polymer and are provided prepackaged in color-coded cartridges, which are provided as single-use, sterile devices.

F. Indications for Use

The Hem-o-lok™ Purple*Plus*™ Large Polymer Ligating Clips are intended for use in procedures involving the 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™ Purple*Plus*™ Large Polymer Ligating Clips are contraindicated for use as a fallopian contraceptive tubal occlusion device.

Hem-o-lok™ Purple*Plus*™ Large Polymer Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

The use of Hem-o-lok™ Purple*Plus*™ Large Polymer Ligating Clips with any other ligation system is contraindicated due to their incompatibility.

H. Environmental Conditions

Hem-o-lok™ Purple*Plus*™ Large Polymer Ligating Clips are "MR Safe" and pose no known hazards in MR environments.

I. Substantial Equivalence

The proposed Hem-o-lok™ Purple*Plus*™ Large Polymer Ligating Clips are substantially equivalent to the predicate device with respect to technology, intended use, indications and technological characteristics:

	New Submission	**Primary Predicate**	**Equivalence**
510(k) Number	K251054	K232970	N/A
Device Name	Hem-o-lok™ Purple*Plus*™ Large Polymer Ligating Clips	Hem-o-lok™ Ligating Clips	N/A
Product Code	FZP	FZP	Identical
Regulation	878.4300	878.4300	Identical
Intended Use	Ligation of vessels and tissue structures		Identical
Indications for Use	The Hem-o-lok™ Purple*Plus*™ Large Polymer Ligating Clips are intended for use in procedures involving the 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.	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™ Purple*Plus*™ Large Polymer Ligating Clips are contraindicated for use as a fallopian contraceptive tubal occlusion device. Hem-o-lok™ Purple*Plus*™ Large Polymer Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies. The use of Hem-o-lok™ Purple*Plus*™ Large Polymer Ligating Clips with any other ligation system is contraindicated due to their incompatibility.	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.	Equivalent

	New Submission	Primary Predicate	Equivalence
Clip Size Offering	Large	Medium, Medium-Large, Large, Extra-Large	Equivalent
Clip Material	Acetal Polymer	Acetal Polymer	Identical
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	Equivalent
Cartridge Design	Color Coded, Easy Load with lateral springs	Color Coded, Easy Load with lateral springs	Equivalent
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 the following has been conducted following product sterilization, environmental conditioning, simulated distribution, and accelerated aging in order to ensure the device performed equivalently to the predicate.

- Clip Latching
- Clip Resistance to Leakage
- Clip Removal

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™ Purple*Plus*™ Large Polymer Ligating Clip is substantially equivalent in performance to the predicate device cleared to market via 510(k) K232970. The proposed device does not introduce any new issues of safety and effectiveness.