November 20, 2025

Hangzhou Kangji Medical Instrument Co., Ltd.
% Esther Zhang
Official Correspondent
Shanghai Ling Fu Technology Co., Ltd.
4F No. 585-2, Wanyuan Rd. Minhang District
Shanghai,
China

Re: K250643
Trade/Device Name: Disposable Polymer Ligation Clips
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: October 21, 2025
Received: October 21, 2025

Dear Esther Zhang:

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,

Alexander Nguyen -S

for 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)*
K250643

Device Name
Disposable polymer ligation clips

Indications for Use *(Describe)*
The Disposable Polymer Ligation 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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510(k) summary

I Submitter

Device submitter: Hangzhou Kangji Medical Instrument Co., Ltd.
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Date prepared: Nov 20, 2025

II Device

Trade Name of Device: Disposable polymer ligation clips
Common Name: ligation clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product code: FZP
Review Panel: General and Plastic Surgery

III Correspondent

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4F No. 585-2, Wanyuan Rd. Minhang District, Shanghai, P.R.China
Contact: Esther ZHANG
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IV Device description

The Disposable polymer ligation clips includes Polymer Clips and Multiple polymer clips. The devices are sterilized by EO, single-use, non-absorbable, non-active implantable devices designed for use in general surgical procedures that require vessel or tissue ligation. The Disposable polymer ligation clips are compatible with the reusable, non-sterile Clip appliers which are made by Kangji. The clips are placed around the tissue and closed with the grip of a clip applier. These clips are made of medical grade acetyl homopolymer and supplied in different sizes and packaged in different clip quantity.

Polymer Clips are housed in a colored cartridge which is consist of base and platen. The clips shall be placed and fired in clip applier one by one. Polymer Clips are available in four sizes: M, ML, L, XL.

Multiple polymer clips (model: KJ-JZJDML, KJ-JZJDL, KJ-JZJDXL) are available in 3 sizes (ML, L, XL), housed in a colored cartridge and has 3 clips which can be placed in clip applier in one time and fired constantly totally 3 times.

Multiple polymer clips (except model: KJ-JZJDML, KJ-JZJDL, KJ-JZJDXL) are available in ML and L size, housed in a striped cartridge. The cartridge which contains 5-15 clips will be placed in clip applier. The clips will be delivered individually advance after each firing.

V Indications for use

The Disposable polymer ligation 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.

VI Substantial Equivalence

The proposed Disposable polymer ligation clips are substantially equivalent to the predicate devices:

Model of proposed device	**Predicate device**	**Manufacturer**	**510(k) No.**
Polymer Clips	Hem-O-Lok® ligation clips	Weck Closure Systems	K993157
Multiple Polymer Clips	Weck Auto Endo5® 5mm Automatic Endoscopic 35cm Applier (Hem-o-lok® ligating clips)	Teleflex Medical Incorporated	K230480

Table 1 compares the model-Polymer clips to the Hem-O-Lok® ligation clips(Weck Closure Systems) with respect to intended use, and technological characteristics, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 1 Comparison of Polymer clips to the predicate device

Device feature	Predicate Device K993157 (Hem-O-Lok®)	Subject Device (Polymer Clips, Multiple Polymer Clips (model: KJ-JZJDML, KJ-JZJDL, KJ-JZJDXL))	Comment
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.	It is 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.	Equivalent
Product code	FZP	FZP	Equivalent
Reuse durability	Single use	Single use	Equivalent
Sterility	EtO at 10^{-6} SAL	EtO at 10^{-6} SAL	Equivalent
Size	M, ML, L, XL	M, ML, L, XL	Equivalent
Composition	Polyacetal	Acetyl homopolymer (which is the same as Polyacetal)	Equivalent
Processing	Injection molding	Injection molding	Equivalent

Conclusion:

The subject and predicate device have the same intended use. The technological characteristics of this product are believed to be substantially equivalent as those for the predicate device. This device and its predicate are substantially equivalent in material and manufacturing methods. The subject and predicate device designs are nearly identical. There are no new questions raised regarding to safety and effectiveness.

Table 2 compares the model-Multiple polymer clips to the Weck Auto Endo5® 5mm Automatic Endoscopic 35cm Applier (Hem-o-lok® ligating clips)(Teleflex Medical Incorporated) with respect to intended use, and technological characteristics, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 2 Comparison of Multiple polymer clips to the predicate device

Device feature	**Predicate Device K230480 (Hem-o-lok® ligating clips)**	**Subject Device (Multiple Polymer Clips)**	**Comment**
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.	It is 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.	Equivalent
Product code	FZP	FZP	Equivalent
Reuse durability	Single use	Single use	Equivalent
Sterility	EtO at 10^{-6} SAL	EtO at 10^{-6} SAL	Equivalent
Size	ML	ML, L	Equivalent
Amount of clip in a cartridge	15	5 to 15	Difference comment 1
Composition	Polymer	Acetyl homopolymer (which is the same as Polyacetal)	Equivalent
Processing	Injection molding	Injection molding	Equivalent
Packaging	The clips are housed in a cartridge and preloaded	The clips are housed in a cartridge and packed	Difference comment 2

Device feature	Predicate Device K230480 (Hem-o-lok® ligating clips)	Subject Device (Multiple Polymer Clips)	Comment
	inside the clip applier	in a dialysis paper with Tyvek coted	

Comment 1

Subject device has a wider range of amount of clip in a cartridge than predicate device, which can provide more choice for surgical clips quantity demand. Surgeons will make decision on how many clips are needed. This difference does not affect the basic design principle, usage, effectiveness and safety of the subject device. There are no new questions raised regarding to safety and effectiveness.

Comment 2

The packing way of two devices is different. they are both housed in a cartridge, while the predicate device is housed in a cartridge and preloaded in the clip applier and the subject device comes separately from the clip applier in its own sterile packaging. The subject will be placed in a clip applier after tearing off the primary package. And then the use of clips relies on the clip applier which is same as the predicate device. The package was addressed by ISO 11607-1, ISO 11607-2 and ASTM F1980 to maintain the sterility of product. This difference does not affect the basic design principle, usage, effectiveness and safety of the subject device. There are no new questions raised regarding to safety and effectiveness.

Conclusion:

The Multiple Polymer Clips and Hem-o-lok® ligating clips in predicate device have the same intended use. The technological characteristics of this product are believed to be substantially equivalent as those for the predicate device. This device and its predicate are substantially equivalent in material and manufacturing methods. The subject and predicate device designs are nearly identical. The differences in technological characteristics between the subject and predicate devices (i.e., different size, amount, packing way) do not raise new questions of safety and effectiveness.

Summary of comparison with the predicate devices:

The subject and predicate devices have the same intended use and application. The subject and predicate device designs are nearly identical. They are single-use devices. The differences in technological characteristics between the subject and predicate devices (i.e., different size, packing way) do not raise new questions of safety and effectiveness.

VII Summary of non-clinical testing

Performance testing

The Disposable polymer ligation clips has been evaluated through performance studies and bench testing, as attached in Appendix C. Testing encompassed appearance, dimension, assembly firmness, matching performance, locking performance, toughness, clamping performance, tensile performance, pressure endurance performance. All the test results were assessed and deemed substantially equivalent to the predicate device.

Biocompatibility testing

Biocompatibility of the Disposable polymer ligation clips was evaluated in accordance with ISO 10993-1:2018 for the body contact category.

Table 3 List of biocompatibility test

Item	Biological endpoints	Standard	Test result
1	Cytotoxicity	ISO 10993-5:2009	Pass
2	Sensitization	ISO 10993-10:2021	Pass
3	Irritation	ISO 10993-23:2021	Pass
4	Material mediated pyrogenicity	ISO 10993-11:2017	Pass
5	Implantation effects	ISO 10993-6:2016	Pass
6	Chemical characterization	10993-18:2020/Amd 1:2022	Pass
7	Toxicological risk assessment	ISO 10993-17:2023	Pass

Sterilization and shelf life testing

- EO sterilization validation per EN ISO 11135-1, 11737-1,11737-2
- Transportation test per ISTA 2A:2011 and ISTA 3A:2018
- Packaging validation per ISO 11607-1/-2
- The 3 years shelf life of the device is determined based on stability study which includes ageing test.
- Bacterial Endotoxin Testing per USP-NF:2023 <85>

VIII Summary of clinical testing

None.

IX Conclusion

The Disposable polymer ligation clips are substantially equivalent to its predicate devices. The differences between the predicate and subject device do not raise any new or different questions of safety or effectiveness. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.