



FDA U.S. FOOD & DRUG
ADMINISTRATION

June 18, 2026

Micro-Energy Medical Technology Co., Ltd.
Danning Zhu
Registered Engineer
Section B4301, B4701 And B4901, # 13, Baolan Rd.
Kengzi St., Pingshan District
Shenzhen, Guangdong 518118
China

Re: K261701

Trade/Device Name: Hemolase Fiber (Hemo-R-0.40-2.5/Hemo-R-0.60-2.5/Hemo-R-0.40-1.8/Hemo-R-0.60-1.8)

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: May 22, 2026

Received: May 22, 2026

Dear Danning Zhu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

TANISHA Digitally signed by
TANISHA L. HITHE -S
L. HITHE -S Date: 2026.06.18
16:54:23 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261701

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Please provide the device trade name(s).

?

Hemolase Fiber (Hemo-R-0.40-2.5/Hemo-R-0.60-2.5/Hemo-R-0.40-1.8/Hemo-R-0.60-1.8)

Please provide your Indications for Use below.

?

Hemolase Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500nm - 2200nm have received regulatory clearance. Hemolase Fibers are intended for use with any cleared surgical laser with an SMA 905 connector.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

Neonates/Newborns (Birth to < 29 days old)

Infants (29 days old to < 2 years old)

Children (2 years old to < 12 years old)

Adolescents (12 years old to < 22 years old)

Adults (22 years old and greater)

?

510(k) Summary:K261701

Date Prepared:May.22nd,2026

This summary of 510(k) information is submitted as required by requirements of 21 CFR §807.92.

1. Submitter's Information

Name of Sponsor: Micro-Energy Medical Technology Co., Ltd.
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2. Correspondent's Information

Company Name: Micro-Energy Medical Technology Co., Ltd.
Correspondent Name: Danning Zhu
Telephone No.: +86-755-28339524
Email Address: danning.z@micro-energy.com

3. Trade Name, Common Name, Classification

| | |
|----------------------------|---|
| Trade Name: | Hemolase Fiber |
| Common Name: | Sterile Single-use Radial Fiber |
| Model: | Hemo-R-0.40-2.5/Hemo-R-0.60-2.5/Hemo-R-0.40-1.8/Hemo-R-0.60-1.8 |
| Classification Name: | Powered Laser Surgical Instrument |
| Product Code: | GEX |
| Classification Panel: | General & Plastic Surgery |
| Device Class: | II |
| Classification Regulation: | 21 CFR 878.4810 |

4. Identification of Predicate Device(s)

The identified predicates within this submission are as follows:

| | |
|--------------------|--|
| Predicate Device : | 510(k) number:K252745 Trade name:Halo Sterile Single-use Radial Fiber Product code:GEX |
|--------------------|--|

5. Description of the Device

The Hemolase Fibers (Model:Hemo-R-0.60-2.5/Hemo-R-0.40-2.5/Hemo-R-0.40-1.8/Hemo-R-0.60-1.8), as surgical laser fibers, are suitable for use in combination with commercially available diode laser systems with a wavelength ranging from 500nm to 2200nm and equipped with SMA905 connectors. The output power should not exceed 30 W. This device is single use only and sterilized by EO gas. The Hemolase Fibers are intended for general surgical operations such as incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissues in either contact or non - contact mode. The Fiber is radial-typed fiber. The fiber has a flat distal end, and its distal glass tube is conical .

6. Intended Use/Indication for Use

Hemolase Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500nm - 2200nm have received regulatory clearance. Hemolase Fibers are intended for use with any cleared surgical laser with an SMA 905 connector.

7. Technological Characteristics

The Hemolase Fibers (Model:Hemo-R-0.40-2.5/Hemo-R-0.60-2.5/Hemo-R-0.40-1.8/Hemo-R-0.60-1.8) uses the same technology that is utilized in the predicate device. A comparison of technological characteristics is provided in the following table:

| SUBSTANTIAL EQUIVALENCE COMPARISON TABLE | | | |
|---|--|---|---|
| Item | Subject device | Predicate device (K252745) | Comparison |
| Product Code | GEX | GEX | Same |
| Regulation No. | 21 CFR 878.4810 | 21 CFR 878.4810 | Same |
| Class | II | II | Same |
| Device Name | Hemolase Fiber | Halo Sterile Single-use Radial Fiber | NA |
| Device Model | Hemo-R-0.40-2.5/Hemo-R-0.60-2.5/Hemo-R-0.40-1.8/Hemo-R-0.60-1.8 | Halo-R-0.40-2.5/Halo-R-0.60-2.5/Novo-R-0.40-1.8/Novo-R-0.60-1.8 | NA |
| Manufacturer | Micro-Energy Medical Technology Co., Ltd. | Micro-Energy Medical Technology Co., Ltd. | NA |
| Intended Use/Indication for Use | Hemolase Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500nm - 2200nm have received regulatory clearance. Hemolase Fibers are intended for use with any cleared surgical laser with an SMA 905 connector | Halo Sterile Single-use Radial Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500nm - 2200nm have received regulatory clearance. Halo Sterile Single-use Radial Fibers are intended for use with any cleared surgical laser with an SMA 905 connector. | Same Only the trade names are different, while their intended use and indications for use are exactly the same.. |

| | | | |
|----------------------|-------------------|-------------------|------|
| Target Population | Adult | Adult | Same |
| Wavelength Range | 500nm-2200mm | 500nm-2200mm | Same |
| Fiber Core Diameter | 0.40mm 0.60mm | 0.40mm 0.60mm | Same |
| Outer Diameter | 0.9mm 1.3mm | 0.9mm 1.3mm | Same |
| Maximum Output Power | 1-30Watts | 1-30Watts | Same |
| Fiber Core Material | Silica Glass | Silica Glass | Same |
| Connectors | SMA 905 | SMA 905 | Same |
| Single Use | Yes | Yes | Same |
| Sterility | EO gas sterilized | EO gas sterilized | Same |
| Biocompatibility | ISO10993 | ISO10993 | Same |

As seen in the comparison tables, The Hemolase Fibers that are the subject of this premarket notification use same technology as that of the Halo Sterile Single-use Radial Fiber of the K252745 510(k). And performance testing demonstrates that the Hemolase Fibers can be used safely and effectively for the proposed indications for use..The Hemolase Fibers are considered to be substantially equivalent to the predicate K252745.

8. Performance testing

To evaluate the minor structural changes to the distal tip of the fiber transmission body and the distal glass tube of the four new models of Hemolase Fibers covered by this submission, design verification was performed to support the safe and effective use of the fibers.

The following tests were conducted on the four new models:

- Product Appearance
- Product Dimensions
- Maximum Transmission Power
- Transmission Efficiency
- Tensile Strength
- Minimum Bending Working Radius of the Fiber

From a biocompatibility standpoint, the Hemolase Fibers covered by this submission are identical to the predicate device Halo Sterile Single-use Radial Fibers (cleared under K252745), with the same overall product structure and materials.

A biological evaluation was completed for the subject fibers, and it was concluded that there are no biocompatibility risks associated with the product.

9. Brief discussion of clinical tests

No clinical studies were considered necessary and performed.

10. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Micro-Energy Medical Technology Co., Ltd concludes that:

- The indications for use of Hemolase Fibers (Model:Hemo-R-0.40-2.5/Hemo-R-0.60-2.5/Hemo-R-0.40-1.8/Hemo-R-0.60-1.8) are the same as those of the predicate device(K252745). The technological characteristics are the same or similar to those of the predicate device(K252745)..
- Hemolase Fibers (Model:Hemo-R-0.40-2.5/Hemo-R-0.60-2.5/Hemo-R-0.40-1.8/Hemo-R-0.60-1.8) is substantially equivalent to the predicate device(K252745).