December 12, 2025

Micro-Energy Medical Technology Co., Ltd.
Danning Zhu
Registered Engineer
Section B4301, B4701 and B4901, No. 13, Baolan Road
Kengzi Street, Pingshan District
Shenzhen, 518118
China

Re: K252745
Trade/Device Name: Halo Sterile Single-use Radial Fiber (Halo-R-0.40-2.5/Halo-R-0.60-2.5/Novo-R-0.60-1.8/Novo-R-0.40-1.8)
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: August 29, 2025
Received: August 29, 2025

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 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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.12.12 12:03:49 -05'00'

for 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.	K252745

Please provide the device trade name(s).

Halo Sterile Single-use Radial Fiber (Halo-R-0.40-2.5/Halo-R-0.60-2.5/Novo-R-0.60-1.8/Novo-R-0.40-1.8)

Please provide your Indications for Use below.

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.

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary: K252745

Date Prepared:December 12, 2025

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:	Halo Sterile Single-use Radial Fiber
Common Name:	Sterile Single-use Radial Fiber
Model:	Halo-R-0.40-2.5/Halo-R-0.60-2.5/Novo-R-0.60-1.8/Novo-R-0.40-1.8
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:K241643 Trade name:WONTECH Surgical Optic Fibers (BA400/BA400R/BA600/BA600R) Product code:GEX

5. Description of the Device

The Halo Sterile Single - use Radial Fibers (Model: Halo - R - 0.40 - 2.5/Halo - R - 0.60 - 2.5/Novo-R-0.60-1.8/Novo-R-0.40-1.8), as surgical laser fibers, are suitable for use in combination with commercially available diode laser systems with a wavelength ranging from500nm 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 Halo Sterile Single - use Radial 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. In particular, they are designed for endovascular coagulation of blood vessels.The Fiber is radial-typed fiber. The shape of distal end of fiber is conical to radiate laser radially.

6. Intended Use/Indication for Use

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.

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7. Technological Characteristics

The Halo Sterile Single - use Radial Fibers (Model:Halo-R-0.40-2.5/Halo-R-0.60-2.5/Novo-R-0.60-1.8/Novo-R-0.40-1.8) 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 (K241643)**	**Comparision**
Product Code	GEX	GEX	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	Same
Class	II	II	Same
Device Name	Halo Sterile Single-use Radial Fiber	WONTECH Surgical Optic Fibers (BA400/BA400R/BA600/BA600R)	NA
Device Model	Halo-R-0.40-2.5/Halo-R-0.60-2.5/Novo-R-0.60-1.8/Novo-R-0.40-1.8	WONTECH Surgical Optic Fibers	NA
Manufacturer	Micro-Energy Medical Technology Co., Ltd.	WON TECH Co., Ltd.	NA

Intended Use/Indication for Use	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.	WONTECH Surgical Optic Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths Between 500nm - 2200nm have received regulatory clearance. WONTECH Surgical Optic Fibers are intended for use with any cleared surgical laser with an SMA 905 connector.	same
Targer Population	Adult	Adult	Same
Wavelength Range	500nm-2200mm	532nm-2100mm	Same
Fiber Core Diameter	0.40mm（Halo-R-0.40-2.5） 0.60mm（Halo-R-0.60-2.5） 0.40mm（Novo-R-0.40-1.8） 0.60mm（Novo-R-0.60-1.8）	0.40mm 0.60mm	Same
Outer Diameter	Halo-R-0.40-2.5:0.9mm Halo-R-0.60-2.5:1.3mm Novo-R-0.40-1.8:0.9mm Novo-R-0.60-1.8:1.3mm	Diameter 0.40mm:0.73mm Diameter 0.60mm:0.75mm	Similar Note01
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 Halo Sterile Single-use Radial Fibers that are the subject of this premarket notification use same or similar technology as that of the WONTECH Surgical Optic Fibers of the K241643 510(k).The minor differences only exist in the outer diameter.Operators can select the products with appropriate outer diameters for the surgery according to the actual situation. The design is intended to meet the claimed requirements of the intended use. Such differences will not give rise to any issues regarding safety and effectiveness. And performance testing demonstrates that the Halo Sterile Single-use Radial Fibers can be used safely and effectively for the proposed indications for use. Moreover, both the subject devices and the predicate devices meet the same standard ISO10993.The Halo Sterile Single-use Radial Fibers are considered to be substantially equivalent to the predicate K241643.

8. Non-Clinical Test Summary

1)Sterilization
The proposed device met all design specifications. Standard written in the sterilization test report are:
1 ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Requirements for the development,validation and routine control of a sterilization process for medical devices
1) ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1:
2) Determination of a population of microorganisms on products
4) ISO 11737-2:2019 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
5) ISO 11138-1:2017 Sterilization of health care products - Biological indicators - Part 1: General requirements
6) ISO 11138-2:2017 sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
7) ISO 11138-7:2019 Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results
8) ISO 10993-7: 2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
9) ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials
10) ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
11) ASTM F2096-11(2019) Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
12) ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
13) ANSI/AAMI ST72:2019 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing
14) ISO 2859-1:1999 Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

2)Software Validation
There is no software available for this device.

3)Biocompatibility
The biocompatibility evaluation for Halo Sterile Single-use Radial Fiber was conducted in accordance with the International Standard ISO 10993‑1:2020, "Biological evaluation of medical devices ‑ Part 1: Evaluation and testing within a risk management process" as recommended by FDA. The biocompatible testing included the following tests:

- Cytotoxicity– (ISO 10993‑5: 2009)
- Skin Sensitization – (ISO 10993‑10:2021)
- Intracutaneous Injection Irritation– (ISO 10993‑23:2021)
- Material-mediated Pyrogens– (ISO 10993-11:2017)
- Acute Systemic Toxicity – (ISO 10993‑11:2017)
- Thrombosis Test in Vivo– (ISO 10993-4:2017)
- Partial Thromboplastin Time (PTT) – (ISO 10993-4: 2017)

- In Vitro Hemolysis Study– (ISO 10993-4: 2017)
- Complement activity– (ISO 10993-4: 2017)
- Bacterial Reverse Mutation– (ISO 10993-3: 2014)
- In vitro Mammalian Chromosome Aberration– (ISO 10993-3: 2014)

4)Performance testing

Performance testing was conducted on Halo Sterile Single-use Radial Fiber. Technical parameters about Packaging Performance,dimension, Maximum Transmission Power,Transmission Efficiency ,Transmission Efficiency,Tensile Strength,Minimum Bending Working Radius of the Fiber were evaluated in the performance testing. All of the tested parameters met the predefined acceptance criteria.

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 Halo Sterile Single-use Radial Fiber (model:Halo-0.40-2.5/Halo-0.60-2.5//Novo-R-0.40-1.8/Novo-R-0.60-1.8) are the same as those of the predicate device. The technological characteristics are the same or similar to those of the predicate device.
- Halo Sterile Single-use Radial Fiber (model:Halo-0.40-2.5/Halo-0.60-2.5/Novo-R-0.40-1.8/ Novo-R-0.60-1.8) is substantially equivalent to the predicate device.