January 8, 2024

WON TECH Co., Ltd.
Hyun Yoon
General Manager
64 Techno8-ro, Yuseong-gu
Daejeon, 34028
Korea, South

Re: K232106
Trade/Device Name: Air Gap Fiber
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: July 14, 2023
Received: August 2, 2023

Dear Hyun Yoon:

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,

Tanisha L. Hithe -S
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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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232106

Device Name
WONTECH Air Gap Fibers

Indications for Use *(Describe)*
The WONTECH Air Gap Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 980 - 2200 nanometers have received regulatory clearance. The Air Gap Fiber delivery devices are intended for use with any surgical laser configured with an SMA-905 connector.

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.

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510(k) Summary

[As required by 21 CFR 807.92]

K232106

1. Date Prepared [21 CFR 807.92(a)(a)]

December 21th, 2023

2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: WON TECH Co., Ltd.
- Address: 64 Techno 8-ro, Yuseong-gu, Daejeon, 34028, Republic of Korea
- Contact Name: Hyun Sik Yoon
- Telephone No.: +82-10-6750-5346
- Fax No.: +82-70-7836-0110
- Email Address: yoonhs21@wtlaser.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Common name: Laser, Fiber Optic Cable
Trade name: Air Gap Fiber

Classification Description	21 CFR Section	Product Code
Powered Laser Surgical Instrument	878.4810	GEX

As stated in 21 CFR, parts 878.4810, the generic type of devices has been classified as Class II.

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate device #1

- 510(k) Number: K170366
- Applicant: Laser Peripherals LLC
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: Family of Bare Laser Fibers

5. Description of the Device [21 CFR 807.92(a)(4)]

The WONTECH Air Gap Fibers are available in 3 sizes. These are 272, 365 and 550 microns and designated as hard clad silica/silica material. These sizes refer to the core diameters of the silica. All fibers are Low OH (hydroxide), especially adapted to delivering wavelengths of laser that are highly absorbed by water. However, for those wavelengths in which water absorption is not a limiting factor, Low OH fiber optic cables may be used as well. The fiber assemblies are configured with standardized SMA-905 connectors, which are the most commonly found connectors in use today. These Air Gap fibers are packaged in sterile, single use, peel away pouches for direct use in operating theaters. The Air Gap fibers are indicated for soft and hard tissue contact and prepared with a polished, flat distal end. The length of the Air Gap fibers is standardized at 3 meters. These Air Gap Fibers may be used with laser outputs from 1-120 watts. The Air Gap Fibers are intended for use in laser surgical procedures including open, laparoscopic or endoscopic ablation, coagulation, incision, and excision or vaporizing in any soft/hard-tissue application for which compatible lasers are applicable.

6. Indications for Use [21 CFR 807.92(a)(5)]

The WONTECH Air Gap Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 980 - 2200 nanometers have received regulatory clearance. The Air Gap Fiber delivery devices are intended for use with any surgical laser configured with an SMA-905 connector.

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7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between Air Gap Fiber and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics.

	Proposed Device	Predicate Device #1	SE Decision
K Number	-	K170366	-
Manufacturer	WON TECH Co., Ltd.	Laser Peripherals LLC	-
Model	Air Gap Fiber	Family of Bare Laser Fibers	-
Intended Use	The WONTECH Air Gap Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500 - 2200 nanometers have received regulatory clearance. The Air Gap Fiber delivery devices are intended for use with any surgical laser configured with an SMA-905 connector.	The Laser Peripherals Laser Fiber is indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500 - 2200 nanometers have received regulatory clearance. The Laser Peripherals Laser Fiber delivery devices are intended for use with any surgical laser configured with an SMA-905 connector.	Same
Material	Silica Core & Cladding, Fluoropolymer buffer. Boot is PVC	Silica Core & Cladding, Fluoropolymer buffer. Boot is PVC	Same
Numerical Aperture	0.22 – 0.048	0.22 – 0.048	Same
Fiber Material	Low Hydroxide	Low Hydroxide	Same
Configuration Tip	Flat	Flat	Same
Use	Universal handpieces, endoscopes, cannulas	Universal handpieces, endoscopes, cannulas	Same
Core Sizes	272, 365 and 550 microns	272, 365 and 550 microns	Same
Laser Power Range	1 to 120 watts	1 to300 watts	Similar but the range of the proposed device is included in the range of the predicate device.
Suitable Laser Wavelengths	980 to 2200 nanometers	500 to 2200 nanometers	Similar but the range of the proposed device is included in the range of the predicate device.

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Laser Compatibility	Any cleared or approved lasers	Any cleared or approved lasers	Same

The WONTECH Air Gap Fibers are substantially equivalent to the predicate device.

The accompanying table of comparison details the specification of the predicate (K170366) Laser Peripherals, LLC Family of Laser Fibers and the proposed device.

This table compares the intended use, features, and technological characteristics of the proposed subject device and the predicate.

The Intended Uses for the WONTECH Air Gap Fibers and the predicate devices are not different in any evaluative manner.

The WONTECH Air Gap Fibers are similar to the predicate devices in that all make almost identical claims. These differences are not critical to the intended therapeutic, surgical use of the device and do not raise any new issues of safety or efficacy. Wavelength range does not vary between the predicate devices.

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Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Sterilization

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

Standard (Edition)	Standard Title
ISO 11737-2 2019	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 11737-1:2018	Sterilization of health care products – Microbiological methods – Part 1. Determination of a population of microorganisms on products.
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ISO 11135:2014/Amd 1:2018	Sterilization of health care products -- Ethylene oxide -Requirements for development, validation and routine control of a sterilization process for medical devices

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2) Software Validation

There is no software available for this device.

3) Biocompatibility

Part	Material	Patient Contact	Duration of Contact by ISO 10993-1	Bio-compatibility
Fiber	Silica Core	Blood path, indirect tissue/ bone/dentin.	Limited (< 24 hours)	Yes

4) Packaging

The packaging of the Air Gap Fiber is validated according to those standards mentioned avobe

No.	Test Item	Standard	Report. No.	Result
1	Packaging dye penetration test	ASTM F1929-15 – Standard Test Method for Detecting Seal Leaks in Porous	2023-GPR-060	No Leak

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		Medical Packaging by Dye Penetration		
2	Packing sealing strength test	ASTM F88/F88M-15 – Standard Test Method for Seal Strength of Flexible Barrier Materials	2023-GPR-059	Pass

5) Performance Testing

The performance of Air Gap Fiber has been defined as follows.

- Accuracy and Stability
- Bend Radius and tensile

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Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification WON TECH Co., Ltd. concludes that Air Gap Fiber is substantially equivalent to predicate devices as described herein.