February 14, 2025

WONTECH Co., Ltd
Hyun Sik Yoon
General Manager
64 Techno-8ro, Yuseong-gu
Daejeon, 34028
Korea, South

Re: K241643
Trade/Device Name: WONTECH Surgical Optic Fibers (BA400/BA400R/BA600/BA600R)
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: January 14, 2025
Received: January 14, 2025

Dear Hyun Sik 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.

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 L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.02.14 21:53:02 -05'00'

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

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.

Submission Number *(if known)*

K241643

Device Name

WONTECH Surgical Optic Fibers (BA400/BA400R/BA600/BA600R)

Indications for Use *(Describe)*

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.

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]

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

June 5th, 2024

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: WONTECH Surgical Optic Fiber
Trade name: BA400/BA400R/BA600/BA600R

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

- 510(k) Number: K220189
- Applicant: Omni-Guide Holdings, Inc
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: LISA Laser Surgical Fibers

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

WT-SMA-400(or BA400)/WT-SMA-600(or BA600)/BA400R/BA600R as surgical laser fiber is indicated for use in general surgical applications of incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in a contact or non-contact mode with a compatible laser system marketed for use in the desired application. Especially, they are indented for endovascular coagulation of blood vessels. WT-SMA-400(or BA400)/WT-SMA-600(or BA600) is bare-typed fiber and BA400R/BA600R is radial-typed fiber. The shape of distal end of fiber is different between bare and radial fiber. Bare fiber distal end is flat to radiate laser straightly, but radial fiber distal end is conical to radiate laser radially.

Additionally, BA400 and BA600 have same design with the each original model(WT-SMA-400 and WT-SMA-600). The additional model name(BA400 and BA600) and each original model name(WT-SMA-400 and WT-SMA-600) need to be alternatively exchanged and labeled depending on customer requirement.

WT-SMA-400(or BA400)/WT-SMA-600(or BA600)/BA400R/BA600R are indicated for use with laser devices emitting radiation from 532 nm to 2100 nm, with pulsed and continuous wave (CW) emission mode and output power less than 30 W.

They are indicated, but not limited, for use with Diode laser, Argon, KTP/532, Ho;YAG, Nd;YAG, Tm:YAG pulsed and continuous wave CW laser devices. They were designed to be connected with laser medical device consisted with SMA905 connector according to IEC 61754-22 and output power less than 30 W.

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

WONTECH Surgical Optic Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 532nm - 2200nm have received regulatory clearance. WONTECH Surgical Optic Fibers are intended for use with any cleared surgical laser 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)]

	Proposed Device	Predicate Device #1	SE Decision
K Number	-	K220189	-
Manufacturer	WON TECH Co., Ltd.	Omni-Guide Holdings, Inc.	-
Model	WONTECH Surgical Optic Fibers	Omni-Guide LISA Laser Surgical Fibers	-
Indications for Use	WONTECH Surgical Optic Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 532nm - 2200nm have received regulatory clearance. WONTECH Surgical Optic 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, SMA 906 connector, or manufacturer specific connectors and adapters.	Similar, the only difference is types of supported connector.
Laser Source	Use with any cleared surgical laser with an SMA 905 connector.	Use with any cleared surgical laser with an SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adapters.	Similar, the only difference is types of supported connector.
Connectors	SMA 905	SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adapters.	Similar, but the specification of proposed device is included in the range of predicate device.
Wavelength	532nm – 2100nm	500nm – 2100nm	Similar, but the specification of proposed device is included in the range of predicate device.
Maximum Power	1-30 Watts	1-300 Watts	Same
Fiber Sizes	400 and 600 microns	Fibers are offered in a range of sizes suitable to user needs.	Similar/Equivalent
Outer Diameter	Diameter 400 microns : 730 microns Diameter 600 microns : 750 microns	Core diameters are offered in a range of sizes suitable to user needs	Similar/Equivalent
Fiber Core Material	Silica Glass	Fused Silica	Similar/Equivalent
Single Use	Yes	Yes	Same
Sterile	Yes	Yes	Same
Sterilizaton	EO gas	EO gas	Same

Method			

The WONTECH Surgical Optic Fibers that are the subject of this premarket notification use identical or similar technology as that of the single-use fibers of the K220189 510(k). Differences between the proposed and predicate fibers do not raise new types of concerns for safety and effectiveness, and performance testing demonstrates that the InnoVoyce single-use optical fibers can be used safely and effectively for the proposed indications for use. The WONTECH Surgical Optic Fibers are considered to be substantially equivalent to the predicate K220189.

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 written in the sterilization test report are;

1 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

2 EN 556-1:2001/AC:2006, Sterilization of medical devices- requirements for medical devices to be designated “STERILE”-Part1: Requirements for terminally sterilized medical devices

3 ISO 11138-1:2017, Sterilization of health care products - Biological indicators – Part 1: General requirements

4 ISO 11138-2:2017, Sterilization of health care products - Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

5 ISO 11737-1:2018, Sterilization of health care products -- Microbiological methods Part 1: Determination of a population of microorganisms on products

6 ISO 11737-2:2019, Sterilization of medical devices - Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of sterilization process.

7 ISO 11607-1:2019, Packaging for terminally sterilized medical device Part1: Requirements for materials, sterile barrier systems and packaging systems

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8 ISO 11607-2:2019, Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes

9 ISO 11140-1:2014, Sterilization of health care products -- Chemical indicators – Part 1: General requirements

10 EN 1422:2014, Sterilizers for purposes - ethylene oxide sterilizers - specification

11 ISO 10993-7:2008/Amd 1:2019, Biological evaluation of medical devices – Part 7 : ethylene oxide sterilization residuals

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 WONTECH Surgical Optic Fibers 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 Medical Packaging by Dye Penetration	2022-GPR-172 2022-GPR-208 2022-GPR-226	No Leak
2	Packing sealing strength test	ASTM F88/F88M-15 – Standard Test Method for Seal Strength of Flexible Barrier Materials	2022-GPR-171 2022-GPR-207 2022-GPR-225	Pass

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

No clinical studies were considered necessary and performed.

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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 WONTECH Surgical Optic Fibers are substantially equivalent to predicate devices as described herein.