May 25, 2022

InnoVoyce LLC
% Cori Ragan
Principal Advisor, Regulatory and Quality System
Labcorp
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416-1334

Re: K220793
Trade/Device Name: InnoVoyce Laser 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: March 16, 2022
Received: March 18, 2022

Dear Cori Ragan:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Purva Pandya, D.Eng.
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)*
K220793

Device Name
InnoVoyce Laser Fiber

Indications for Use *(Describe)*

InnoVoyce Laser Fiber is intended for use in incision/excision, vaporization, ablation, and coagulation of soft tissue.

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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5.0 TRADITIONAL 510(K) SUMMARY

I. Submitter Information

Submitted by:	Labcorp
Contact Person:	Cori Ragan Principal Advisor Labcorp 5353 Wayzata Boulevard, Suite 505 Minneapolis, Minnesota 55416 Telephone: 612-268-8746 Cori.Ragan@labcorp.com
Date of Summary:	May 23, 2022

II. Device Information

Device Trade Name:	InnoVoyce Laser Fiber
Common or Usual Name:	Surgical laser instrument
Classification Name:	878.4810 - Laser surgical instrument for use in general and plastic surgery and in dermatology.
Class:	2
Product Code:	GEX
Review Panel:	General & Plastic Surgery
Model Number:	S-00102-300, S-00103-400, S-00104-600

III. Predicate Information

Predicate Device:	LISA Laser Surgical Fiber
Company:	Omni-Guide Holding, Inc.
510(k) Number:	K220189
Common or Usual Name:	Surgical laser instrument
Classification Name:	878.4810 - Laser surgical instrument for use in general and plastic surgery and in dermatology.
Class:	2
Product Code:	GEX
Review Panel:	General & Plastic Surgery

IV. Device Description

The InnoVoyce Laser Fibers are sterile, single use, disposable laser delivery devices designed to deliver laser energy at 532 nm (KTP) for use in incision/excision, vaporization, ablation, and coagulation of soft tissue. The laser fibers are used as an accessory to the Aura KTP medical laser.

They are 12 feet (3.66m) long glass fibers in flexible jackets, and they are available in three sizes 300, 400, and 600 Microns. The choice of the fiber diameter is dependent upon the surgical procedure, the desired tissue effects, and the personal preference of the surgeon. Fibers with small core diameters minimize lateral tissue damage, are more flexible, and tend to cut faster when used in contact than larger diameter fibers.

The InnoVoyce Laser Fibers have a proprietary connector meeting the Aura XP surgical laser console interface requirements which includes: custom bayonet-style engagement to the system, and fiber model recognition. The InnoVoyce Laser Fibers transmit maximum power available from the Aura XP at 15w. This fiber within the surgical laser system will be operated by a surgeon and a laser safety officer.

V. Indication for Use

InnoVoyce Laser Fiber is intended for use in incision/excision, vaporization, ablation, and coagulation of soft tissue.

VI. Substantial Equivalence

A comparison of the technological characteristics of the predicate and subject device is given in **Table 5-1** below:

Table 5-1: Substantial Equivalence

Device	Subject Device – InnoVoyce Laser Fiber	Predicate Device – LISA Laser Surgical Fibers (K220189)	Equivalence
Indications or intended use	InnoVoyce Laser Fiber is intended for use in incision/excision, vaporization, ablation, and coagulation of soft tissue.	Omni-Guide Holdings, Inc. single-use LISA Laser Surgical Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500nm - 2200nm have received regulatory clearance. Omni-Guide Holdings, Inc. single-use LISA Laser Surgical Fibers devices are intended for use with any cleared surgical laser with an SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adapters.	Similar/Equivalent
Product Code	GEX	GEX	Same
Classification Name	878.4810 - Laser surgical instrument for use in general and plastic surgery and in dermatology.	878.4810 - Laser surgical instrument for use in general and plastic surgery and in dermatology.	Same
Classification	Class II	Class II	Same
Use of Device	Rx Only	Rx Only	Same
Laser Source	Aura XP surgical laser console	Use with any cleared surgical laser with an SMA 905 connector, SMA 906 connector, or manufacturer specific connectors and adapters.	Different. No new or increse risk and no impact to safety and effectiveness when used with applicable laser source.

Connectors	Propietary	SMA 905 and SMA 906	Different. No new or increse risk and equivalent safety and effectiveness when used with a compatible laser system containing an applicable connector.
Wavelength	532 nm	532nm–2100nm	Same (within range of predicate)
Maximum Power	15W	1-300 Watts	Same (within range of predicate)
Fiber Sizes	300, 400, and 600 microns	Fibers are offered in a range of sizes suitable to user needs	Similar/Equivalent
Outer Diameter	300 = 1.2 Fr 400 = 1.7 Fr 600 = 2.3 Fr	Core diameters are offered in a range of sizes suitable to user needs	Similar/Equivalent
Fiber Core Material	Silica Glass	Fused Silica	Similar/Equivalent
Jacket Material	ETFE	Nylon, Polyimide, or Teflon	Similar/Equivalent
Single Use	Yes	Yes	Same
Sterile	Yes	Yes	Same
Sterilization method	EO	EO	Same

VII. Performance Data

Non-Clinical Performance Testing:

Non-clinical testing was performed on InnoVoyce Laser Fiber, (the subject device) and demonstrates compliance with the following International and FDA-recognized consensus standards:

- ISO 14971:2007 - Medical devices – Application of risk management to medical devices
- ISO-10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-7:2008 - Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- USP <161> - MEDICAL DEVICES—BACTERIAL ENDOTOXIN AND PYROGEN TESTS
- ISO 11135:2014/Amd.1:2018 - Sterilization of health-care products—Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - AMENDMENT 1: Revision of Annex E, Single batch release
- ISO 11138-2:2017 - Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
- ISO 11737-1:2018 - Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
- ISO 11607-1:2019 - Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019 - Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.

The subject device was tested in accordance with Verification and Validation processes in accordance with design control practices. Testing has been performed to address intended use, the technological characteristics, requirement specifications, and the risk management results.

Clinical Data:

No clinical testing was required to demonstrate safety or effectiveness for the subject device as the device's non-clinical (bench) testing was sufficient to support the intended use of the device.

VIII. Conclusion

The InnoVoyce single-use optical 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 InnoVoyce single-use optical fibers are considered to be substantially equivalent to the predicate K220189.