May 29, 2024

InnoVoyce
% Thompson Aubrey
Regulatory Consultant
Hoy and Associates Regulatory Consulting
1830 Bonnie Way
Sacramento, California 95825

Re: K240159
Trade/Device Name: InnoVoyce VYLO
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: April 25, 2024
Received: April 25, 2024

Dear Thompson Aubrey:

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
Digitally signed by Tanisha L. Hithe -S
Date: 2024.05.29 23:22:25 -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

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.

Submission Number *(if known)*

K240159

Device Name

InnoVoyce VYLO

Indications for Use *(Describe)*

The InnoVoyce VYLO is intended for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. Suggested applications include:

General Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue as well as in endoscopic (e.g., laparoscopic) or open surgeries.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract; esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; gastrointestinal hemostasis (including varices, espohagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, gastric erosions); gastrointestinal tissue ablation (benign and malignant neoplasm, angiodysplasia, polyps, ulcer, colitis, hemorrhoids).

Gynecology: Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: endometriosis; cervical, vulvar, and vaginal intraepithelial neoplasia; condyloma acuminata; uterine septum; intrauterine adhesions; submucosal fibroids.

Head and Neck/ Otorhinolaryngology (ENT): Tissue incision, excision, ablation, and vessel hemostasis.

Neurosurgery: Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

Ophthalmology:
Post-vitrectomy endophotocoagulation of the retina.

Plastic Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

Spinal Surgery: Percutaneous lumbar diskectomy.

Thoracic Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

Urology: Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: bladder, urethral & ureteral tumors; condylomas; lesions of external genitalia; urethral & penile; hemangioma; urethral strictures; bladder neck obstructions; and vaporization of prostate tissue for men suffering from benign prostate hyperplasia/ hypoplasia (BPH).

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.

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510(K) Summary
InnoVoyce VYLO
K240159

Applicant	InnoVoyce, LLC
Address	One Beacon Street, Floor 15 Boston, MA 02108
Sponsor Contact	Stephen Mais Stephen.mais@innovoyce.com
Regulatory Contact	Aubrey Thompson, Regulatory Consultant Aubreythompson@hoyregulatory.com
Preparation Date	May 22, 2024
Device Trade Name	InnoVoyce VYLO
K Number	K240159
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code	GEX
Regulatory Class	II
Legally Marketed Predicate Device	Greenlight XPS Laser System K092735

Device Description:
InnoVoyce VYLO is a solid-state laser device with laser energy generated by internal diodes. The laser output energy of the device is in the blue spectrum at wavelength of 445-465nm.

The system is intended to be used by professional practitioners (specialized physician/ authorized technical personnel) in the medical field. The system is intended for use in professional healthcare facility environments.

Indications for use:

The InnoVoyce VYLO is intended for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. Suggested applications include:

General Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue as well as in endoscopic (e.g., laparoscopic) or open surgeries.

Gastroenterology: Tissue ablation and hemostasis in the gastrointestinal tract;

esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; gastrointestinal hemostasis (including varices, espohagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, gastric erosions); gastrointestinal tissue ablation (benign and malignant neoplasm, angiodysplasia, polyps, ulcer, colitis, hemorrhoids).

Gynecology: Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: endometriosis; cervical, vulvar, and vaginal intraepithelial neoplasia; condyloma acuminata; uterine septum; intrauterine adhesions; submucosal fibroids.

Head and Neck/ Otorhinolaryngology (ENT): Tissue incision, excision, ablation, and vessel hemostasis.

Neurosurgery: Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.

Ophthalmology: Post-vitrectomy endophotocoagulation of the retina.

Plastic Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue in endoscopic and open procedures.

Spinal Surgery: Percutaneous lumbar diskectomy.

Thoracic Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures.

Urology: Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: bladder, urethral & ureteral tumors; condylomas; lesions of external genitalia; urethral & penile; hemangioma; urethral strictures; bladder neck obstructions; and vaporization of prostate tissue for men suffering from benign prostate hyperplasia/ hypoplasia (BPH).

Device Comparison – Indications for use and Technical Specifications:

Specification	Subject Device K240159	Predicate Device – Greenlight XPS Laser System (K092735)	Comparison
Indications for use	The InnoVoyce VYLO is intended for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. Suggested applications include: **General Surgery:** Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue as well as in endoscopic (e.g., laparoscopic) or open surgeries. **Gastroenterology:** Tissue ablation and hemostasis in the gastrointestinal tract; esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; gastrointestinal hemostasis (including varices, espohagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers,	The GreenLight XPS Laser System is intended for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. Suggested applications include: **General Surgery:** Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue as well as in endoscopic (e.g., laparoscopic) or open surgeries. **Gastroenterology:** Tissue ablation and hemostasis in the gastrointestinal tract; esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; gastrointestinal hemostasis (including varices, espohagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers,	Same

Specification	Subject Device K240159	Predicate Device – Greenlight XPS Laser System (K092735)	Comparison
	gastric erosions); gastrointestinal tissue ablation (benign and malignant neoplasm, angiodysplasia, polyps, ulcer, colitis, hemorrhoids). **Gynecology:** Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: endometriosis; cervical, vulvar, and vaginal intraepithelial neoplasia; condyloma acuminata; uterine septum; intrauterine adhesions; submucosal fibroids. **Head and Neck/ Otorhinolaryngology (ENT):** Tissue incision, excision, ablation, and vessel hemostasis. **Neurosurgery:** Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type. **Ophthalmology:** Post-vitrectomy endophotocoagulation of the retina.	non-bleeding ulcers, gastric erosions); gastrointestinal tissue ablation (benign and malignant neoplasm, angiodysplasia, polyps, ulcer, colitis, hemorrhoids). **Gynecology:** Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as: endometriosis; cervical, vulvar, and vaginal ntraepithelial neoplasia; condyloma acuminata; uterine septum; intrauterine adhesions; submucosal fibroids. **Head and Neck/ Otorhinolaryngology (ENT):** Tissue incision, excision, ablation, and vessel hemostasis. **Neurosurgery:** Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type. **Ophthalmology**: Post-vitrectomy endophotocoagulation of the retina.	

Specification	Subject Device K240159	Predicate Device – Greenlight XPS Laser System (K092735)	Comparison
	Plastic Surgery: Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue in endoscopic and open procedures. **Spinal Surgery:** Percutaneous lumbar diskectomy. **Thoracic Surgery:** Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures. **Urology**: Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: bladder, urethral & ureteral tumors; condylomas; lesions of external genitalia; urethral & penile; hemangioma; urethral strictures; bladder neck obstructions; and vaporization of prostate tissue for men suffering from benign prostate hyperplasia/ hypoplasia (BPH).	**Plastic Surgery:** Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue in endoscopic and open procedures. **Spinal Surgery:** Percutaneous lumbar diskectomy. **Thoracic Surgery:** Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue, including lung tissue in thoroscopic or open procedures. **Urology**: Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of: bladder, urethral & ureteral tumors; condylomas; lesions of external genitalia; urethral & penile; hemangioma; urethral strictures; bladder neck obstructions; and vaporization of prostate tissue for men suffering from benign prostate hyperplasia/hypoplasia (BPH).	

Specification	Subject Device K240159	Predicate Device – Greenlight XPS Laser System (K092735)	Comparison
Laser Type	Diode Laser	KTP Laser	Different.
Laser Power	Up to 30 W	Up to 180W	Different. See discussion below.
Wavelength	455nm +/-10nm	532nm	Different. Absorption spectra are very close for 532nm and 455nm, and performance testing shows comparable performance for the desired indications.
Laser Class	4	4	Same
Operation Mode	Continuous Wave, pulsed wave, Quasi-pulsed wave, Quasi-continuous wave	Unknown	Different. Performance testing was conducted with CW and QC-W for the VYLO to represent worst case.

Specification	Subject Device K240159	Predicate Device – Greenlight XPS Laser System (K092735)	Comparison
			See testing discussion below.
Pulse Length/Duration	1ms to 200ms (operation mode dependent) and continuous wave	Unknown	Different. See discussion below.
Repetition Rate	Up to 1000 pulses per second (quasi-continuous mode)	Unknown	Different. See discussion below.
Fluence	300µm: 5,163 – 51,629 J/cm^2 400µm: 2,867 – 28,671 J/cm^2 600µm: 1,263 – 12,627 J/cm^2	Unknown	Different. See testing discussion below.
Aiming Beam Wavelength	515nm	Unknown	Different. Though slightly different in wavelength, both produce similar visible light for the aiming beam
Aiming Beam Power	5mW	5mW	same
Optical Fiber Core Diameter	300µm fiber: 272µm core diameter 400µm fiber: 365µm core diameter 600µm fiber: 550µm core diameter	Unknown	Different. See discussion below.
Cooling	Internal coolant	Unknown	Different

Specification	Subject Device K240159	Predicate Device – Greenlight XPS Laser System (K092735)	Comparison
Display	Touchscreen	Touchscreen	Same
Main Power Supply	100VAC to 240VAC +/- 10% 50Hz to 60Hz <5A	Unknown 47-63 Hz 1.06-0.45 A	Same

Discussion
The InnoVoyce VYLO is a 30W 455nm Diode surgical laser, and the Greenlight XPS (Predicate Device) is a 180W 532nm potassium-titanyl-phosphate (**KTP**) surgical laser. Both are intended for the surgical incision/excision, vaporization, ablation, hemostasis, and coagulation of soft tissue. Both devices are comprised of a base unit, an applicator, and handheld laser optical fibers ("**LOF**s"). In the case of VYLO, LOFs are sterile, single use, disposable devices designed to deliver the laser's energy. VYLO LOFs are available in three different diameters: 300, 400, and 600 microns. The output settings of the laser can be adjusted by the user. The VYLO's base unit is a console with a graphical touch screen user interface and a footswitch, and single-use, disposable LOFs. The system has four laser emission modes: Continuous Wave (CW), Pulsed Wave (PW), Quasi Pulsed Wave (QPW), and Quasi Continuous Wave (QCW). The Greenlight XPS functions on the same principles with some differences.

Electrical Safety, Electromagnetic Compatibility, and Software

The Electrical Safety and Electromagnetic compatibility tests were performed in accordance with the following standards.

- IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-22 Edition 3.1 2012-10, Medical electrical equipment – part 2-22: Particular requirements for basic safety and essential performance of surgical cosmetic therapeutic and diagnostic laser equipment
- IEC 60825-1 Edition 2.0 2007-03, Safety of Laser Products – Part 1: Equipment classification and requirements
- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes
  Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.
- EN ISO 14971:2019+A11:2021; Medical Devices – Application of Risk Management To Medical Devices
- IEC TR 60601-4-2 Edition 1.0 2016-05; Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Clinical Evidence – N/A. No clinical studies were conducted as part of this submission.

Performance Testing
Performance testing was conducted to verify the pulse width, power output, and repetition rate. Histology testing was conducted side by side with the predicate device to demonstrate performance in a worst case scenario. Testing was conducted using the cleared laser fiber.

Performance Testing Summary

For the VYLO device, 300 and 600 microns LOFs were tested at 30 W in CW mode ~ 2 mm distance and 3 mm/sec translation speed to mimic the worst case. For the 600 microns LOFs, testing at 20 W at CW and Q-CW was also performed. All settings mentioned above were triplicated in all three types of tissues (liver, kidney, and muscle) as recommended by FDA guidance for Industry for Premarket Notification.

The predicate device was assessed side-by-side to the VYLO at Q-CW emission mode at two power levels 30 and 180 W. 30 W mimics the max power level of the VYLO device, and 180 W is maximum power level the Predicate is cleared for. The Predicate was also tested on all three types of test tissues and each setting was triplicated. All other treatment parameters were also identical (at 37C, 2 mm distance from the surface, and 3 mm/sec translation speed).

The study demonstrated that the treatments produced clearly detectable Coagulation and Ablation Zones (**CAZs**) in all three treated tissues at all dose levels for both devices. Dimensions of the CAZs were not significantly different when 300- and 600- microns tips were used. Increasing the power level from 20- to 30 W did not significantly influence the thermally damage profiles produced by the VYLO Device. Relatively shallower CAZ's were observed for the VYLO Device when treatment was performed on Q-CW vs CW at the same power level. The dimensions of the CAZs produced by the Predicate Device at 30 W were in close proximity to the CAZs produced by the VYLO Device at 30 W. However, the dimensions of the CAZs produced by the Predicate Device at its maximum power level (180 W) were larger (deeper and wider) than damage produced by the VYLO Device at its maximum power level. These data are consistent across all three types of test tissue specimens.

The obtained data allows one to conclude the VYLO's thermal damage profiles were consistent across all three test specimens for all tested parameters. The study also demonstrated the ability of the VYLO to deliver consistent thermal damage profiles comparable to the profiles produced by the Predicate Device at the similar power level. The dimensions of CAZs of the VYLO Device at the worst cases (max power level) are relatively smaller than the dimensions of the CAZs for the Predicate Device. Thus, it can be concluded that treatment by the VYLO device at the maximum dose settings will provide a similar clinical effect to the Predicate Device in a safer and more controlled way, because the lesions profiles at worst cases (at max power levels 30 W at CW vs. 180 W at Q-CW) for the VYLO Device is smaller compared to Predicate device. It can be concluded that treatment by such a device at the appropriate testing settings will possess a desirable clinical treatment effect.

Conclusion

The safety and effectiveness determination between the subject and the predicate devices is supported by the performance data provided in the submission. The electrical and EMC testing, the software verification and validation testing and the non-clinical bench tests demonstrate that the InnoVoyce VYLO performs comparably to the predicate device that is currently marketed for the same intended use. Based on the performance testing of the two devices, it can be determined that they are substantially equivalent.