February 4, 2022

Intersect ENT
Yoko Enrile
Advisor, Regulatory Affairs
1555 Adams Dr.
Menlo Park, California 94025

Re: K212774
Trade/Device Name: VenSure LightGuide
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, And Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: January 7, 2022
Received: January 10, 2022

Dear Yoko Enrile:

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,

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K212774

Device Name
VenSure™ LightGuide

Indications for Use *(Describe)*
The VenSure™ LightGuide is used to locate, illuminate within, and transilluminate across, nasal and sinus structures in adults.

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.

510(k) Summary

510(k) Number: K212774

Date prepared: February 2, 2022

1.Submitter Information

Submitter:	Intersect ENT
Address:	1555 Adams Dr.
	Menlo Park, CA 94025, USA
Telephone:	(650) 681 3143
Fax:	(650) 641 2065
Contact:	Yoko Enrile
	Advisor, Regulatory Affairs

2.Device Information

Trade Name:	VenSure™ LightGuide
Common Name:	Sinus Guidewire
Classification:	Class I per 21 CFR 874.4420
Classification Name:	Ear, nose and throat manual surgical instrument
Product Code:	LRC

3.Predicate Device Information

The VenSure™ LightGuide is substantially equivalent to PathAssist LED Light Fiber (K141916).

4.Device Description

VenSure™ LightGuide is a sterile, single-use device designed to emit light from the distal end. The device is an accessory to the VenSure™ Balloon device and used to locate, illuminate within and transilluminate across nasal and sinus structures. The device consists of a flexible light fiber, a protective sheath and an integrated battery-powered LED light source. When activated, the light fiber will emit red light from the distal tip for two (2) hours. It has a fiber nominal working length of 20mm (0.79 inch) with an outer diameter of 0.5mm (0.02 inch). The VenSure™ LightGuide is packaged separately.

5. Intended Use

The VenSure™ LightGuide and the predicate device have the same Intended Use, which is to locate, illuminate within, and transilluminate across, nasal and sinus structures.

Indications for Use for VenSure™ LightGuide and Predicate Device

Device	Indications for Use
VenSure™ LightGuide – Subject device	The VenSure™ LightGuide is used to locate, illuminate within, and transilluminate across, nasal and sinus structures in adults.
PathAssist LED Light Fiber (K141916) – Predicate device	To locate, illuminate within, and transilluminate across nasal and sinus structures in patients aged 18 and over.

6. Comparison of Technological Characteristics

The VenSure™ LightGuide is substantially equivalent to PathAssist LED Light Fiber (K141916). The VenSure™ LightGuide has the same intended use and fundamental scientific technology as the predicate device (K141916). The subject device has the same technological characteristics; in particular, basic design, energy source, performance, and principle of operation.

Description	VenSure™ LightGuide - Subject Device	PathAssist LED Light Fiber (K141916) - Predicate Device
Device Classification	Class I, LRC, 21 CFR 874.4420	Class I, LRC, 21 CFR 874.4420
Indications for use	See above	See above
Light fiber dimensions	OD: 0.5mm Length: 304mm	OD: 0.375mm Length: 276mm
Device Design	Device consists of a flexible light fiber, a protective sheath/housing and an integrated battery-powered LED light source	Device consists of a flexible light fiber, a protective sheath and an integrated battery-powered LED light source
Biocompatibility	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1
Sterilization	Ethylene Oxide	Ethylene Oxide
Battery Type	Lithium Manganese Dioxide, CR2, 3 Volts	Lithium Manganese Dioxide, CR2, 3 Volts
Light Source Type	LED (Red)	LED (Red)
Maximum LED Power Output	1 W	1 W
Light Source Wavelength / Color	625nm / Red	625nm / Red
Medical Safety Standards	Complied with IEC 60601-1	Complied with IEC 60601-1

Description	VenSure™ LightGuide - Subject Device	PathAssist LED Light Fiber (K141916) - Predicate Device
Medical EMC Standard	Complied with IEC 60601-1-2; Type BF applied part	Complied with IEC 60601-1-2; Type BF applied part
Illumination and activation time	Emits red LED light from the distal end of light fiber for 2 hours	Emits red LED light from the distal end of light fiber for over 60 minutes
Use	Single use, disposable	Single use, disposable
Operation Method	Load the light fiber into Sinus Dilation Device (VenSure Balloon Sinus Dilation System) and attach the light fiber housing to the luer lock fitting on the VenSure Balloon device. Pull the tab to activate the LED light.	Load the light fiber into Sinus Dilation Device (XprESS Multi-Sinus Dilation System) and attach the LED light fiber housing to the barbed fitting of XprESS device. Pull the tab to activate the LED light.

The performance testing including mechanical integrity, functionality, EMC and Electrical Safety testing / evaluation support that the difference in the fiber dimensions and activation time between the subject device and the predicate device do not raise any new concerns of safety or effectiveness.

7. Performance Data

Bench Testing

Bench testing was conducted to ensure that the VenSure™ LightGuide met the predefined acceptance criteria to demonstrate safety and performance. Testing included the following:

- Dimensional and Slider Characterization
- Light Output and Run Time Test
- Slider Separation Force
- Advancement and Retraction Force
- Light Fiber Tensile
- Comparative Light Output Testing against the predicate device

All tests met the predefined acceptance criteria. The test results demonstrated that differences in device characteristics between the subject device and predicate device do not raise any new questions of safety or effectiveness.

Biocompatibility

The biocompatibility evaluation for the VenSure™ LightGuide was conducted in accordance with ISO 10993-1. Biocompatibility testing included cytotoxicity, irritation, sensitization and acute systemic toxicity testing. All tests successfully met the required acceptance criteria, demonstrating that the patient contacting materials used in the subject device are biocompatible.

Sterilization & Stability

Sterilization validation testing was performed to demonstrate compliance with ISO 11135-1. Shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

Electromagnetic compatibility and Electrical Safety

Electromagnetic Compatibility (EMC) and Electrical Safety testing was conducted per IEC 60601-1 and IEC 60601-1-2.

8. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, it is concluded that the VenSure™ LightGuide performs as its intended use, is substantially equivalent to the predicate device identified in this submission and does not present any new issues of safety or effectiveness.