May 26, 2023

Fiagon GmbH
Dirk Mucha
CTO
Neuendorfst. 23b
Hennigsdorf, Brandenburg 16761
Germany

Re: K230065
Trade/Device Name: VenSure™ Balloon Dilation System, VenSure™ Light Balloon Dilation System, VenSure™ Nav Balloon Dilation System, VenSure™ ET Balloon Dilation System
Regulation Number: 21 CFR 874.4180
Regulation Name: Eustachian Tube Balloon Dilation System
Regulatory Class: Class II
Product Code: PNZ, LRC
Dated: April 25, 2023
Received: April 25, 2023

Dear Dirk Mucha:

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,

Joyce C. Lin -S

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)*
K230065

Device Name
VenSure™ Balloon Dilation System, VenSure™ Light Balloon Dilation System, VenSure™ Nav Balloon Dilation System, VenSure™ ET Balloon Dilation System

Indications for Use *(Describe)*
The VenSure™ Balloon Dilation System is used to access and treat the frontal ostia/recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.
To dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in adult patients using a transnasal approach.

The VenSure™ Nav Balloon Dilation System is additionally intended for use in conjunction with the Cube Navigation System during ENT procedures when surgical navigation or image-guided surgery may be necessary to locate the Eustachian tube or to locate tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses to facilitate dilation of the sinus ostia.

The VenSure™ Light Balloon Dilation System is additionally 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.

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510(k) Summary

May 25, 2023

1. Submitter Information

Submitter: Fiagon GmbH
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Contact: Dirk Mucha
Chief Technology Officer

2. Device Information

Trade Name: VenSure™
VenSure™ Light
VenSure™ Nav
VenSure™ ET
Collectively: VenSure™ Balloon Dilation System

Eustachian Tube Dilation

Common Name: Eustachian Tube Balloon Dilation Device

Classification: Class II per 21 CFR 874.4180

Classification Name: Eustachian Tube Balloon System (21 CFR 874.4180)

Product Code: PNZ

Sinus Dilation

Common Name: Sinus Dilation Device

Classification: Class I per 21 CFR 874.4420

Classification Name: Ear, nose and throat manual surgical instrument

Product Code: LRC

3. Predicate Device Information

- Primary predicate: XprESS ENT Dilation System (K163509)
- Secondary predicate: VenSure and VenSure Nav Balloon Devices (K201472) with VenSure LightGuide (K212774)

The primary predicate is the predicate device for the added Eustachian Tube indication with product code PNZ, CFR 874.4180. The secondary predicate is the predicate device for sinus balloon dilation with product code LRC, CFR 874.4420.

4. Device Description

The VenSure Balloon Dilation Systems combine features of a malleable suction and a malleable probe with the tissue expansion effect of balloon dilation. The distal end of the device includes an atraumatic tip and can be shaped to fit the Frontal, Maxillary, Sphenoid sinuses, and Eustachian tube using the Bending Tool provided with the device. Since the distal end of the device is re-shapeable, one balloon can be modified to work on multiple sinuses and the Eustachian tube within the same patient. The devices come in an EO sterilized tray sealed inside of a Tyvek pouch with the bending tool, inflation device, and extension line included in the tray.

All VenSure versions enable a physician to track the device into the sinuses and eustachian tube using endoscopic visualization.

The **VenSure™ Nav** allows additionally for image-guided visualization when connected to the Cube Navigation System (manufactured by Fiagon). The VenSure™ Nav contains an integrated sensor carrier that enables the use of image guidance through "plug and play" tracking capability when used with the Fiagon Navigation System. The sensor carrier containing localizer elements detects a signal within a low-energy magnetic field delivered from the navigation unit. The navigation software then displays the location of the dilation instrument's tip within multiple patient image planes and other anatomic renderings. After confirmation of placement, the balloon of the dilation device can be inflated with saline solution, using the inflation device to expand the outflow track of the targeted structure.

The **VenSure™ Light** additionally allows for LED light confirmation of the VenSure balloon through transillumination across nasal and sinus structures. The VenSure™ Light has an integrated flexible light fiber with battery powered LED light source designed to emit red light from the distal end of the VenSure balloon.

The **VenSure™ ET** is a 45°- pre-bent configuration of the basic VenSure (with straight balloon tip). The pre-bend to 45°bemt of the VenSure ET facilitates the use of the device when only used for treatment in the eustachian tube. The device however can also be reshaped to fit to the sinuses using the Bending tool.

5. Intended Use

The VenSure™, VenSure™ Light, VenSure™ Nav and VenSure™ ET Balloon Dilation Systems are intended to remodel or recreate the sinus outflow tract and dilate the Eustachian tube by transnasal balloon dilation. They have the same intended use as the primary predicate XprESS (K163509) and similar intended use as the secondary predicate VenSure Balloon Devices (K201472) with VenSure LightGuide (K212774).

Indications for Use for VenSure™ Balloon Dilation System and Predicate Devices

Device	Indications for Use
VenSure™, VenSure™ Light, VenSure™ Nav, and VenSure™ ET Balloon Dilation System	The VenSure™ Balloon Dilation System is used to access and treat the frontal ostia/recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. The balloon devices are used to dilate portions of the Eustachian tube for treating persistent Eustachian tube dysfunction in adult patients using a transnasal approach. The VenSure™ Nav Balloon Dilation System is intended for use in conjunction with the Cube Navigation System during ENT procedures when surgical navigation or image-guided surgery may be necessary to locate the Eustachian tube or to locate tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses to facilitate dilation of the sinus ostia. The VenSure™ Light Balloon Dilation System is used to locate, illuminate within, and transilluminate across, nasal and sinus structures in adults.
VenSure™, VenSure™ Nav Balloon Device (K201472)	The VenSure™ Balloon Device and VenSure™ Nav Balloon Device are used to access and treat the frontal recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. The VenSure™ Nav Balloon Device is intended for use in conjunction with the Fiagon Navigation System during sinus procedures when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses to facilitate dilation of the sinus ostia.
VenSure™ LightGuide (K212774)	The VenSure™ LightGuide is used to locate, illuminate within, and transilluminate across, nasal and sinus structures in adults.
Xpress ENT Dilation System (K163509)	To access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a transnasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. To dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in patients 18 years and older using a transnasal approach.

6. Comparison of Technological Characteristics

The VenSure™, VenSure™ Light, VenSure™ Nav, and VenSure™ ET Balloon Dilation Systems have the same fundamental scientific technology as the predicate devices [K201472 with K212774 and K163509]. The subject devices have the same technological characteristics; in particular, basic design, performance, and principle of operation.

Feature	VenSure™ Balloon Dilation System (VenSure, VenSure Light, VenSure Nav, VenSure ET)	Xpress ENT Dilation System (Entellus/Stryker) [K163509]	VenSure Balloon Dilation Device (VenSure, VenSure Nav) [K201472] with VenSure LightGuide [K212774]	Equivalence
	Subject Device	**Primary Predicate**	**Secondary Predicate**	
Class	Class II 21 CFR 874.4420 21 CFR 874.4180 Product code: PNZ, LRC	Class II 21 CFR 874.4420 21 CFR 874.4180 Product code: PNZ, LRC	Class I 21 CFR 874.4420 Product code: LRC	Equivalent, Same as primary predicate for PNZ Same as secondary predicate for LRC
Indications for Use	(see above)	(see above)	(see above)	Equivalent, Same as primary predicate for PNZ Same as secondary predicate for LRC
Balloon design	Fixed balloon over malleable shaft	Sliding balloon mechanism over malleable shaft	Fixed balloon over malleable shaft	Equivalent, Same
Balloon Dimensions [D x L (mm)]	6 x 18	5 x 8, 5 x 20 6 x 8, 6 x 18, 6 x 20 7 x 18, 7 x 20	6 x 18	Equivalent, Same
Balloon Tip (mm)	Polymer coated ball-tip diameter (dimensions): 1.81	Stainless steel ball-tip diameter (dimensions) Standard: 2 LoProfile: 1.75 Ultra: 1.5	Polymer coated ball-tip diameter (dimensions): 1.63	Equivalent, both subject and predicate devices have a round ball-tip
Endoscopic Visual Distance Indicator	10 mm and 20 mm depth indicator marks printed on balloon shaft	10 mm and 20 mm depth indicator marks printed on balloon shaft	10 mm and 20 mm depth indicator marks printed on balloon shaft	Same
Ability to access multiple locations with single balloon	Yes – tip angle is reshapable using bending tool	Yes – tip angle is reshapable using bending tool	Yes – tip angle is reshapable using bending tool	Same
Inflation Device	Syringe barrel and plunger	Syringe barrel and plunger	Syringe barrel and plunger	Same
Visualization	-Endoscopy -Navigation option (VenSure™ Nav) -Light illumination option (VenSure™ Light)	-Endoscopy -Navigation option (TGS Guidewire) -Light illumination option (PathAssist)	-Endoscopy -Navigation option (VenSure™ Nav) -Light illumination option (VenSure LightGuide)	Equivalent, Same
Image-guided Tracking Method	Electromagnetic (VenSure™ Nav only)	Electromagnetic (optional TGS Guidewire)	Electromagnetic (VenSure™ Nav only)	Equivalent, Same

7. Performance Data

Bench Testing

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

Performance testing	**Criteria for SE justification**
Balloon dimensional integrity	The dimensions of the balloon are as specified and in accordance with the properties of the predicates.
Balloon pressure stability/ Balloon fatigue conditioning test	The burst pressure at end of lifetime is above the rated in use pressure and within the specifications of the predicates.
Balloon Inflation/Deflation times	The balloon inflates and deflates at end of lifetime of the device within the specifications of the predicates.
Balloon burst pressure	The burst pressure is well above the rated in use pressure and within the specifications of the predicates.
Mechanical integrity	Mechanical properties all met predefined acceptance criteria. It can be demonstrated that the minor differences in dimensions to the secondary predicate do not raise new concerns of safety and effectiveness and can be rated as substantial equivalent.
Catheter and distal tip geometries characterization	The specified catheter and distal tip geometries are within the range of the primary predicate devices.
Simulated use testing in clinical model	Same design safety features and mechanically functionality as primary predicate device can be demonstrated.
Navigation compatibility (VenSure™ Nav only)	Navigation accuracy is within the rating of the secondary predicate.
LightGuide compatibility and performance	Dimensions and light output performance are within the ratings of the secondary predicate.

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

Biocompatibility

The biocompatibility evaluation for the VenSure™ Balloon Dilation Systems was conducted in accordance with FDA recognized consensus standard ISO 10993-1:2018. 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 devices 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.

Navigation Compatibility (VenSure™ Nav)

Bench testing was conducted to determine the imaging accuracy of the device (VenSure™ Nav). Test results demonstrate functionality and compatibility with the Fiagon Navigation system and support the claim of substantial equivalence to the secondary predicate.

Electromagnetic compatibility and Electrical Safety

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

8. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, it is concluded that the VenSure™ Balloon Dilation Systems are substantially equivalent to the predicate devices identified in this submission, and do not present any new issues of safety or effectiveness.