August 26, 2020

Fiagon GmbH
Dirk Mucha
Chief Technology Officer
Neuendorfstrasse 23b
16761 Hennigsdorf
Germany

Re: K201472
Trade/Device Name: VenSure Balloon Device, VenSure Nav Balloon Device
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, And Throat Manual Surgical Instrument
Regulatory Class: Class I, reserved
Product Code: LRC
Dated: June 2, 2020
Received: June 3, 2020

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,

Malvina B. Eydelman, M.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201472

Device Name
VenSure™ Balloon Device
VenSure™ Nav Balloon Device

Indications for Use *(Describe)*
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.

The Fiagon Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Fiagon Navigation system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery can be identified relative to a CT or MR based model of the anatomy.

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

August 11, 2020

1. Submitter Information

Submitter: Fiagon GmbH
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Telephone: +49 3302 201 21 10
Telefax: +49 3302 201 21 15

Contact: Dirk Mucha
Chief Technology Officer

2. Device Information

Trade Name:	VenSure™ Balloon Device VenSure™ Nav Balloon Device
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

The VenSure™ Balloon Device and VenSure™ Nav Balloon Device are substantially equivalent to the following predicate devices:

- Primary predicate: XprESS Multi-Sinus Dilation Tool (K142252)
- Secondary predicate: Medtronic EM Sinus Dilation System (K132297)

4. Device Description

Fiagon's VenSure™ Balloon Device and VenSure™ Nav Balloon Device are sterile, single-use devices designed to remodel the bony structures within the sinuses. The device comes in two versions a navigation ready version (VenSure™ Nav) that is compatible with the Fiagon electromagnetic navigation system, and a basic non-navigation ready version (VenSure™).

The VenSure™ and VenSure™ Nav devices, 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, and sphenoid sinuses 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 within the same patient.

Both versions enable a physician to track the device into the sinuses using endoscopic visualization; while the VenSure™ Nav allows for image-guided visualization when connected to the Fiagon Navigation System. 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 sinus 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 inflator to expand the outflow track of the targeted sinus.

A suction tube may be connected directly to the proximal luer fitting of the basic VenSure™ balloon dilation device to provide active suction. Alternately, an Extension Line connected to a syringe may be connected directly to the proximal luer fitting to provide irrigation. Suction and irrigation are not possible on the VenSure™ Nav.

5. Intended Use

The VenSure™ and VenSure™ Nav and the predicate devices have the same Intended Use, which is to access and treat the frontal, maxillary and sphenoid sinuses using a transnasal approach.

The Indications for Use for the VenSure™ and VenSure™ Nav Balloon Devices are the same as the XprESS Multi-Sinus Dilation Tube. Both, the VenSure™ Nav and the Medtronic EM Sinus Dilation System have an additional indication for use with a compatible image-guided navigation system (Fiagon Navigation System) as an aid for locating anatomical structures in either open or percutaneous procedures.

Indications for Use for VenSure™ / VenSure™ Nav and Predicate Devices

Device	Indications for Use
VenSure™ Balloon Device VenSure™ Nav Balloon Device	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. The Fiagon Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Fiagon Navigation system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery can be identified relative to a CT or MR based model of the anatomy.
Xpress Multi-Sinus Dilation Tool (K142252)	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.

Device	Indications for Use
EM Sinus Dilation System / (K132297)	The EM Sinus Dilation System is intended for use in sinus procedures when surgical navigation or image-guided surgery may be necessary to locate and remove tissue, bone or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, and sphenoid sinuses. The EM Sinus Dilation system is used in conjunction with the Medtronic computer-assisted surgery system. The Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT- or MR-based model, or digitized landmarks of the anatomy. The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise or judgment.

6. Comparison of Technological Characteristics

The VenSure™ and VenSure™ Nav Balloon Devices have the same fundamental scientific technology as the predicate devices [K142252 and K132297]. The subject devices have the same technological characteristics; in particular, basic design, performance, and principle of operation.

Feature	VenSure™ and VenSure™ Nav Balloon Device	Xpress Multi-Sinus Dilation Tool [K142252]	EM Sinus Dilation System [K132297]	Equivalence
Class	Class I 21 CFR 874.4420 Product code: LRC	Class I 21 CFR 874.4420 Product code: LRC	Class I 21 CFR 874.4420 Product code: LRC	Same
Indications for Use	(see above)	(see above)	(see above)	Equivalent For Dilation same as Predicate 1 For image guidance same as Predicate 2
Balloon design	Fixed balloon	Sliding balloon mechanism	Fixed balloon	Same as Predicate 1
Balloon Dimensions [D x L (mm)]	6 x 18	5 x 8, 5 x 18, 5 x 20, 6 x 8, 6 x 18, 6 x 20, 7 x 18	5 x 7, 6 x 7, 7 x 7 5 x 17, 6 x 17, 7 x 17	Equivalent Same size available in Predicate 1 Less additional sizes are available
Ability to access multiple locations with single balloon?	Yes – tip angle is reshapable using bending tool	Yes – tip angle is reshapable using bending tool	N/A - Rigid tip. Multiple versions of device with fixed balloon shapes based on sinus.	Same as Predicate 1
Inflation Device	Syringe barrel and plunger	Syringe barrel and plunger	Syringe barrel and plunger	Same
Visualization	Endoscopy & Image guided option (VenSure™ Nav)	Endoscopy	Endoscopy & Image guided option (	Same as Predicate 2
Image-guided Tracking Method	Electromagnetic (VenSure™ Nav only)	N/A (Compatible)	Electromagnetic	Same

7. Performance Data

Bench Testing

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

- Balloon dimensional integrity
- Balloon pressure stability /Inflation/Deflation
- Inflation and Deflation Time
- Mechanical integrity
    - Torsion strength
    - Tensile force
    - Dimensions
- Navigation compatibility (VenSure™ Nav only)

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™ and VenSure™ Nav balloon dilation devices was conducted in accordance with FDA recognized consensus standard ISO 10993-1:2009. 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 & Shelf Life

Validation of the sterilization cycle has been conducted in accordance with ISO 11135:2014, ISO10993-7:2018, ISO 11737-1:2018.

Shelf life and packaging testing were performed to support the labeled shelf life:

- Accelerated aging study has been performed (ASTM F 1980) and in parallel a real-time aging study was started
- package integrity was determined by:(referenced standards: ISO11607-1, ASTM F1886, ASTM F88, ASTM F1140, ASTM F1929)
- packaging system performance testing was performed according to reference standard ISTA-2A.

All tests were successfully completed. Real time aging study has been started.

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 predicate, Medtronic EM Sinus Dilation System.

Electromagnetic Compatibility

The device VenSure™ Nav is used in connection with the Fiagon Navigation system. Compliance to IEC 60601-1-2, 4th edition of the new device could be demonstrated by leveraging existing data of cleared navigation probes used with the Fiagon Navigation System.

8. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, Fiagon GmbH demonstrated that the VenSure™ and VenSure™ Nav are substantially equivalent to the predicate devices identified in this submission, and they are as safe and perform in an equivalent manner to the stated predicate devices.