June 1, 2026

VisionAir Solutions
Jacob Marsh
Product Development Engineer
1800 Triplett Blvd.
Akron, Ohio 44306

Re: K261541
Trade/Device Name: VisionAir Enhanced Stock Stent
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: NWA
Dated: May 8, 2026
Received: May 8, 2026

Dear Jacob Marsh:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261541

Please provide the device trade name(s).

VisionAir Enhanced Stock Stent

Please provide your Indications for Use below.

The VisionAir Enhanced Stock Stent is indicated for the treatment of adults ≥22 years of age with symptomatic stenosis of the airway. The Enhanced Stock stent is intended for implantation into the airway by a physician using the recommended deployment system or an equivalent rigid bronchoscope and stent placement system that accepts the maximum stent diameter being placed. The stent is intended to be in the patient up to 12 months after initial placement.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Premarket Notification:

Tracheal Prosthesis - Enhanced Stock Stent

VisionAir Solutions

510(k) Summary

The following 510(k) Summary is provided in accordance with 21 CFR 807.92.

510(k) Owner and Registration

Owner's Name:	Theken Companies, LLC Subsidiary: VisionAir Solutions
Address:	1800 Triplett Blvd., Akron, OH 44306
Phone Number:	(330) 733-7600
Fax Number:	(330) 733-7602
Date Summary Prepared:	05/29/2026
Establishment Registration Number:	3010197296

510(k) Contact

Contact:	VisionAir Solutions
Address:	1800 Triplett Blvd., Akron, OH 44306
Phone Number:	330-733-7600
Fax Number:	330-733-7600
Contact Person:	Jacob Marsh

Device Name and Classification

Device Trade Name:	VisionAir Solutions Enhanced Stock Stent
Device Common Name:	Tracheal prosthesis
Regulation Number and Description:	21 CFR 878.3720
Device Class:	Class II
Product Codes:	NWA

Legally Marketed Predicate

The VisionAir Solutions Patient-Specific Stent is considered the predicate device.

Company	**Predicate Device**	**510(k) Number**
VisionAir Solutions	Patient-Specific Stent	K182743

Device Description

The VisionAir Enhanced Stock Stent (ESS) is an implantable, single-use silicone airway stent designed to treat symptomatic stenosis of the central airway. Unlike traditional stock airway stents, the ESS is geometrically derived from a population model of non-diseased tracheobronchial airway anatomy, enabling an off-the-shelf device that conforms to the natural curvature and cross-sectional geometry of the human airway. The ESS is currently designed for the main carina region of the tracheobronchial airway (Y-stent configuration).

The ESS is the subject device of this Special 510(k) submission. The predicate device for the purposes of this submission is the VisionAir Solutions Patient-Specific Airway Stent (K182743). The subject device is substantially equivalent to the predicate device in intended use and technological characteristics with respect to material, shelf-life, mechanical performance, and deployment method. The key distinction between the subject and predicate device is the subject device is offered is discrete sizes, while the predicate device features a patient-specific design.

The ESS is offered in a discrete set of sizes derived from population model outputs (refer to Section 6). Each size is manufactured using the same silicone injection molding process as the cleared VisionAir Patient-Specific Airway Stent, using the same implant-grade silicone material and the same 3D-printed mold methodology.

Indications for Use:

The VisionAir Enhanced Stock Stent is indicated for the treatment of adults ≥22 years of age with symptomatic stenosis of the airway. The Enhanced Stock stent is intended for implantation into the airway by a physician using the recommended deployment system or an equivalent rigid bronchoscope and stent placement system that accepts the maximum stent diameter being placed. The stent is intended to be in the patient up to 12 months after initial placement.

Summary of Technological Characteristics

The table below provides a comparison of technological characteristics between the Subject and Predicate Devices:

Characteristic	ESS (Subject Device)	VAS Patient-Specific Stent (K182743)	Comparison Result
Indications for Use	The VisionAir Enhanced Stock Stent is indicated for the treatment of adults ≥22 years of age with symptomatic stenosis of the airway. The Enhanced Stock stent is intended for implantation into the airway by a physician using the recommended deployment system or an equivalent rigid bronchoscope and stent placement system that accepts the maximum stent diameter being placed. The stent is intended to be in the patient up to 12 months after initial placement.	The VisionAir Patient-Specific Stent is indicated for the treatment of adults ≥22 years of age with symptomatic stenosis of the airway. The patient-specific silicone stent is intended for implantation into the airway by a physician using the recommended deployment system or an equivalent rigid bronchoscope and stent placement system that accepts the maximum stent diameter being placed. The stent is intended to be in the patient up to 12 months after initial placement.	**Identical**
Material	Implant-grade silicone	Implant-grade silicone	**Identical**

Shelf-life	3-months	3-months	**Identical**
Configuration	3-branch Y-stent	3-branch Y-stent (patient-specific geometry)	**Substantially Equivalent:** Both subject and predicate devices are 3-branch Y-stents intended for use in the tracheobronchial airway; the subject device is offered in discrete fixed sizes while the predicate device is patient-specific.
Geometry	Population-modeled, organic curvature; discrete off-the-shelf sizes	Patient-specific geometry designed via V3D software per individual CT scan	**Substantially Equivalent:** Both devices feature an organic, non-linear tracheobronchial Y-stent configuration. The key distinction is that subject device geometry is derived from a population model of non-diseased airway anatomy and offered in discrete fixed sizes, whereas the predicate device geometry is patient-specific and generated on a per-order basis via VisionAir's cleared software. Performance testing was conducted to confirm that the subject device geometry is compatible with the same deployment system used for the predicate device.
Wall Thickness	Variable nominal wall thickness driven by branch diameter: 1.0 – 1.25 mm ± 0.25 mm	1.0 mm ± 0.25 mm	**Substantially Equivalent:** The subject device has a variable nominal wall thickness of 1.0–1.25 mm ± 0.25 mm, compared with 1.0 mm ± 0.25 mm for the predicate. This difference does not change the material, intended use, deployment method, sterilization status, or duration of use. Bench testing was conducted to evaluate whether the dimensional differences adversely affected device performance.
Anti-Migration Studs	Yes, anterior surface of all branches	Yes, anterior surface of main branch	**Substantially Equivalent:** Both devices feature anti-migration studs on the anterior surface; the subject device extends this feature to all three branches while the predicate device includes studs on the main branch only.

Deployment	Rigid bronchoscope & stent applicator system	Rigid bronchoscope & stent applicator system	**Identical**
Sterilization	Provided nonsterile; steam sterilizable by end user	Provided nonsterile; steam sterilizable by end user	**Identical**
Mfg Process	Silicone injection into 3D-printed mold	Silicone injection into 3D-printed mold	**Identical**

Performance Data

Nonclinical performance testing was conducted to evaluate the subject device and demonstrate substantial equivalence to the predicate device. The following standards were used in support of this submission:

- *Radial Compression Testing* (per ISO 25539-1)
- *Fatigue Testing* (per ISO 25539-1)
- *Stent Loading and Deployment Testing*
- *Biocompatibility* (per ISO 10993-1)
- *Sterilization* (per ANSI AAMI ISO ST79)
- *Accelerated Aging* (per ASTM F1980-21)

Conclusions

The VisionAir Enhanced Stock Stent System has the same indications for use as the predicate device. A comparison of technological characteristics and performance testing demonstrates that VisionAir Enhanced Stock Stent System is substantially equivalent to the predicate device.