New COS Inc. DBA VisionAir Solutions
Keith Grafmeyer
Director of Product Development
7100 Euclid Ave, Ste 180
Cleveland, Ohio 44103

Re: K213969
Trade/Device Name: VisionAir Patient-Specific Airway Stent
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: Class II
Product Code: NWA
Dated: September 2, 2022
Received: September 6, 2022

Dear Keith Grafmeyer:

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 James Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia 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)*
K213969

Device Name
VisionAir Patient-Specific Airway Stent

Indications for Use *(Describe)*
The VisionAir Patient-Specific Airway Stent is indicated for the treatment of adults ≥22 years of age with symptomatic stenosis of the airway. The 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K213969

A. Submitted by:

Keith Grafmeyer
Director of Product Development
New COS, Inc. d.b.a. VisionAir Solutions
7100 Euclid Ave; Ste 180
Cleveland OH, 44103
Tel: (216) 800-5905 x 102

Date Prepared: 06-Oct-2022

B. Device Name

Trade or Proprietary Name:	VisionAir Patient-Specific Airway Stent
Common or Usual Name:	Prosthesis, Tracheal, Preformed/Molded
Classification Name:	Tracheal Prosthesis
Device Class:	Class II
Classification:	21 CFR § 878.3720
Product Code:	NWA

C. Predicate Device

The subject *VisionAir Patient-Specific Airway Stent* is substantially equivalent to the primary predicate device, *Patient-Specific Airway Stent,* cleared in 510(k) K182743. Additionally, reference devices, *Mimics and Osirix MD*, cleared under K073468 and K101342 respectively were used for reference software performance specifications.

D. Device Description:

The subject device, *VisionAir Patient-Specific Airway Stent* is comprised of a cloud-based software suite and the patient-specific airway stent. These two function together as a system to treat symptomatic stenosis of the airway per the indications for use. The implantable patient-specific airway stent is designed by a physician using a CT scan as a guide in the cloud-based software suite. The airway is segmented from the CT scan and used by the physician in designing a patient-specific stent. When design is complete, the stent is manufactured via silicone injection into a 3D-printed mold and delivered to the treating physician nonsterile, to be sterilized before use.

The implantable patient-specific airway stent includes the following general features:

- Deployed through a compatible rigid bronchoscope system
- Made of biocompatible, implant-grade silicone
- Steam sterilizable by the end user
- Anti-migration branched design
- Anti-migration studs on anterior surface of main branch

- Single-use

The cloud-based software suite has the following general features:

- Upload of CT scans
- Segmentation of the airway
- Design of a patient specific stent from segmented airway
- Order management of designed stents

The purpose of this submission is to introduce design modifications to the *Patient-Specific Airway Stent,* originally cleared in 510(k) K182743.

E. Indications for Use

The *VisionAir Patient-Specific Airway Stent* is indicated for the treatment of adults ≥22 years of age with symptomatic stenosis of the airway. The 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.

F. Technological Characteristics

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

Technological Characteristics	**Predicate Device K182743**	**Subject Device K213969**	**Comparison**
Intended Use/Indications for Use	The *Patient-Specific Airway Stent* is indicated for the treatment of adults ≥22 years of age with symptomatic stenosis of the airway. The 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.	The *VisionAir Patient-Specific Airway Stent* is indicated for the treatment of adults ≥22 years of age with symptomatic stenosis of the airway. The 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.	Equivalent
Design Concept	Branched (Y) stent configurations for a specific patient designed by a physician using cloud-based software	Branched (Y) stent configurations for a specific patient designed by a physician using cloud-based software	Equivalent

Technological Characteristics	Predicate Device K182743	Subject Device K213969	Comparison
Deployment method	Common applicator system in conjunction with an appropriate rigid bronchoscope system	Common applicator system in conjunction with an appropriate rigid bronchoscope system	Equivalent
Period of implantation	Up to 12 months	Up to 12 months	Equivalent
Single use	Yes	Yes	Equivalent
Material	Implant-grade silicone	Implant-grade silicone	Equivalent
Sterilization Method	Moist heat	Moist heat	Equivalent
Wall Thickness	Uniform 1.0mm	Uniform 1.0mm	Equivalent
Surface finishing	Smooth interior and exterior surfaces of device with anti-migration studs on anterior surface of main branch of stent	Smooth interior and exterior surfaces of device with anti-migration studs on anterior surface of main branch of stent	Equivalent
Diameter, length and angles	Ability to vary the inner diameter, length and angles along the stent in cloud-based software	Ability to vary the inner diameter, length and angles along the stent in cloud-based software	Equivalent
Jailed airway location	Visual estimation during intraoperative stent fenestration	Indicator on stent preoperatively determined to assist in intraoperative fenestration	Equivalent
Segmentation	CT scan uploaded into cloud-based software for 3D airway model for manual segmentation by trained technician	CT scan uploaded into cloud-based software for 3D airway model for semi-automated segmentation by trained technician	Equivalent*
Workflow	CT upload → segmentation → stent design → stent manufacturing	CT upload → segmentation → stent design with enhanced features → stent manufacturing	Equivalent

*Reference devices, Mimics (K073468) and Osirix MD (K101342) were used to establish substantial equivalence for software performance specifications

G. Performance Data

Nonclinical performance and functional testing were performed to demonstrate that the subject *VisionAir Patient-Specific Airway Stent* is substantially equivalent to its predicate device. The following testing was performed:

- *Sterilization Validation* (per ANSI/AAMI ST79:2017)
- *Tear Strength Testing* (per ISO 34-1:2015)
- *Radial Compression Testing* (per ISO 25539-1:2017)
- *Fatigue Testing* (per ISO 25539-1:2017)
- *Migration Testing*
- *Stent Deployment Testing*
- *Biocompatibility Testing* (per ISO 10993-1:2018)
- *Accelerated Aging Testing* (per ASTM F1980-16:2016)

- *Dimensional Testing of Airway Segmentation* (reference device *Mimics* K073468 used for performance reference specification)
- *Software Verification and Validation Testing*
- *Human Factors and Usability Testing for Web Software*
- *Airway Segmentation Process Testing*

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to Predicate Device, the Subject *VisionAir Patient-specific Airway Stent* has been demonstrated to be substantially equivalent to its Predicate Device cleared by the Agency for commercial distribution in the U.S.