October 23, 2019

New COS Inc.
Keith Grafmeyer
Sr. Project Manager
7100 Euclid Ave, Ste 180
Cleveland, Ohio 44103

Re: K182743
Trade/Device Name: Patient-Specific Airway Stent
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: NWA
Dated: October 17, 2019
Received: October 18, 2019

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,

James J. Lee, Ph.D.
Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182743

Device Name
Patient-Specific Airway Stent

Indications for Use *(Describe)*
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.

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

510(k) OWNER / MANUFACTURER: New COS, Inc.
7100 Euclid Ave
Ste 180
Cleveland OH, 44103

CONTACT PERSON: Keith Grafmeyer
Sr. Product Manager
New COS, Inc.
Tel: (216) 800-5905 x 102
Email: kgrafmeyer@customorthopaedics.com

TRADE NAMES: Patient-Specific Airway Stent

PREPARATION DATE: October 23, 2019

COMMON NAMES: Prosthesis, Tracheal, Preformed/Molded

Product: Patient-Specific Airway Stent System	**Product Code**	**Regulation and Classification Name**	**Device Class**
Patient-Specific Airway Stent	NWA	21 CFR 878.3720 Tracheal Prosthesis	II

PREDICATE DEVICE:

Subject Device: Patient-Specific Airway Stent	Corresponding Predicate Device(s)
Patient-Specific Airway Stent	K971509: ENDOXANE

REFERENCE DEVICES:

Device 510(k) Number	Device Name	Reason for Use
K073468	Mimics	Performance specification for airway segmentation
K894380	Dumon Tracheobronchial Stent	Performance specification for compression strength
K121048	Ultraflex Tracheobronchial Stent System – Sterile Uncovered	Performance specification for compression strength

DEVICE DESCRIPTION:
The Patient-Specific Airway Stent is comprised of Web Software and the Patient-Specific Silicone Y-Stent. These two function together as a system to treat symptomatic stenosis of the airway. The Patient-Specific Silicone Stent is designed by a physician using a CT scan as a guide in the Web Software. The Web Software gives the user (physician) the ability to upload a scan, view the airway, and design a stent. The stent, after physician approval, is manufactured via silicone injection into a 3D-printed mold and delivered to the treating physician's medical center nonsterile.

The Patient-Specific Airway Stent includes the following general features:

- Deployed through a common applicator system in conjunction with an appropriate rigid bronchoscope system
- Made of biocompatible, implant-grade silicone
- Steam sterilizable
- Anti-Migration studs on anterior surface
- Single-use only
- Branched (Y-Stent) to prevent migration
- Designed and approved in a proprietary software by a physician for an individual patient

The Web Software has the following general features:

- Gives COS technicians the ability to segment the airway and automatically calculate a centerline
- Create, edit, and save patient-specific airway stents from segmented airway
- Define exact stent diameters at specific locales
- Measure stent inner and outer diameters at any point along stent design
- CT scan as the imaging input modality
- Physician able to manage patient's stent designs and CT scans
- Physician able to approve stent design through software (create 3D prescription)

INTENDED USE AND INDICATIONS:

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.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Patient-Specific Airway Stent is substantially equivalent to the ENDOXANE stent (K971509) with regards to intended use and indications for use.

The materials used to design the Patient-Specific stent are substantially equivalent to the materials used to manufacture the Endoxane stents and the performance characteristics of the subject device have been tested to show substantial equivalency to the currently marketed predicate device. Biocompatibility testing has confirmed that the Patient-Specific Silicone Stent is acceptable for use as a medical device following the requirements stated in the FDA's Guidance on the Use of ISO 10993-1.

The primary technological difference between the subject and predicate device is the introduction of software to allow a physician to design a stent for a specific patient. The risks introduced by this difference have been mitigated in the software, rendering the subject device's risk profile substantially equivalent to the predicate. Software verification and validation was performed to confirm that the software fully satisfies all inputs.

TECHNOLOGICAL CHARACTERISTICS SUMMARY:
The Patient-Specific Airway Stent is substantially equivalent to the predicate device in terms of technological characteristics including design, materials, and features.

Identical Characteristics

- Branched (Y) stent configurations (no more than 3 branches).
- Method of deployment through a common applicator system in conjunction with an appropriate rigid bronchoscope system based on the maximum outer diameter being deployed.
- Uniform wall thickness option of 1.0mm.
- Visually smooth interior and exterior surfaces of device.
- Removable implant, if necessary (recommended to be replaced after 12 months of implantation).
- Single-use implant only.
- Uniform material composed of biocompatible, implant-grade silicone proven through performance and biocompatibility testing according to ISO 10993-1.
- Sterilizable silicone material via common steam cycle from AAMI ST79.
- Anti-migration studs on anterior surface of main branch of stent.

Technological Differences

- **(Subject)** Stent is designed by a Physician using software for a specific patient vs. **(Predicate)** Stent is chosen from stock designs out of a catalog for a specific patient.
- **(Subject)** Ability to vary the inner diameter of the stent at any location along the stent from 6mm-18mm in 0.1mm increments (patient-specific design with software) vs. **(Predicate)** Discretely vary the inner diameter from 8-18mm in 1.0mm increments (stock stent design from catalog)
- **(Subject)** Ability to vary the length of the stent up to 145mm according to the patient's anatomy vs. **(Predicate)** Ability to vary length up to 110mm based on available stent designs in a catalog
- **(Subject)** 3D-printed molds for silicone injection vs **(Predicate)** Machined molds for silicone injection
- **(Subject)** Secondary branch angle ≤ 100° vs **(Predicate)** Secondary branch angle always 75°
- Subject device has lower flat-plate compression strength than the predicate device

Any risks related to these technological differences have been mitigated to an acceptable level, rendering the subject device substantially equivalent to the predicate device. The technological characteristics, including all design mitigations, have been verified and validated.

NON-CLINCICAL PERFORMANCE TESTING
Performance and functional testing were performed to ensure the Patient-Specific Airway Stent functions according to the inputs and demonstrates substantial equivalence to the predicate device.

- *Sterilization Testing* – Confirms that the subject device can be steam sterilized to a SAL of 10^{-6}, using a common cycle in medical centers.
- *Tear Strength Testing* – Supports the claim that the subject device's material is equivalent to the predicate's material in tear strength.

- *Radial Compression Testing* – Compares the compression strength of the subject device against the predicate device
- *Fatigue Testing* – Supports the claim that the subject device does not fatigue when cyclically compressed over the intended life of the implant (1 year)
- *Stent Deployment Testing* – Supports the claim that the subject device is able to be deployed by a common applicator and rigid bronchoscope system
- *Biocompatibility Testing* – Supports the claim that the subject device is acceptable to implant in terms of biocompatibility for up to one year; identical to the predicate device's permanent implantation duration.
    - Cytotoxicity: MEM Elution Test
    - Sensitization: Guinea Pig Maximization Test
    - Irritation: Intracutaneous Reactivity
    - Toxicity: Acute Systemic Toxicity
    - Pyrogenicity: Material-Mediated Pyrogenicity
    - Subacute/Sub-Chronic Toxicity: Sub-Chronic Intramuscular Implantation in Rabbits for 90days with Histopathology
    - Genotoxicity: Ames Bacterial Reverse Mutation Assay
    - Genotoxicity: Mouse Lymphoma Assay
    - Genotoxicity: In Vivo Mouse Micronucleus Mutagenicity Assay
    - Chemical Characterization of Extractables and Leachables
- *Software Verification and Validation Testing* – Supports the claim that the software functions as designed, including any design mitigations included to reduce risks associated with the addition of software and patient-specific stent creation into the subject device. Per FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the software was classified as a Major level of concern.
- *Human Factors and Usability Testing for Web Software* – Supports the claim that the software is as safe and as effective as the predicate device when used by its intended users in its intended use-environment.
- *Migration Testing* – Bench testing in procedural training model to test migration forces required to dislodge an implanted patient-specific airway stent
- *Accelerated Aging Testing* – Testing to evaluate the shelf-life of the patient-specific airway stents
- *Dimensional Testing of Airway Segmentation* – Evaluated the accuracy of segmented airway rendering in proprietary segmentation software
- *Airway Segmentation Process Validation* – Validated the process of segmenting an airway from a CT scan in proprietary segmentation software

CONCLUSION

The Patient-Specific Airway Stent is substantially equivalent to the predicate device in intended use, indications for use, principle of operation, and technological characteristics.