November 15, 2023

M/s Meril Life Sciences Pvt. Ltd.
Bhavin Choradiya
Senior Manager- Regulatory Affairs
Survey No. 135/139, Bilakhia House,
Muktanand Marg, Chala, Vapi
Vapi, Gujarat 396191
India

Re: K231818
Trade/Device Name: METIC™ Airway Balloon Catheter
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: June 20, 2023
Received: June 21, 2023

Dear Bhavin Choradiya:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231818

Device Name
METIC™ – Airway Balloon Catheter

Indications for Use *(Describe)*
METIC™ – Airway Balloon Catheter is intended to dilate strictures of the airway.

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

Type of 510(k)

Traditional

Submitter

M/s. Meril Life Sciences Private Limited

Survey No. 135/139, Bilakhia House,

Muktanand Marg, Chala, Vapi – 396191 Gujarat, India.

Tel. No: +91-260-3052100, Fax: +91-260-3052125

Web site: www.merillife.com

Establishment Registration No.

3009613036

Contact Person

Dr. Bhavin Choradiya

E-mail: bhavin.choradiya@merillife.com

Device details

Trade Name/ Proprietary Name	**METIC™** – Airway Balloon Catheter
Panel	Airway Dilation Balloon Catheter
Common/ Usual Name	Balloon Dilation Catheter
Classification Name	Bronchoscope (Flexible or Rigid)and Accessories
Regulation Number	21 CFR 874.4680
Classification	Class II
Product Code	KTI

Predicate Device

Subject device	Predicate device		
	Trade Name	**Manufacturer**	**510 (k) No.**
METIC™ – Airway Balloon Catheter	Inspira *Air*® Balloon Dilation System ***(Primary Predicate)***	Acclarent Inc.	K090660
	Aeris® Balloon Dilation Catheter ***(Second Predicate)***	Bryan Medical Inc.	K150951

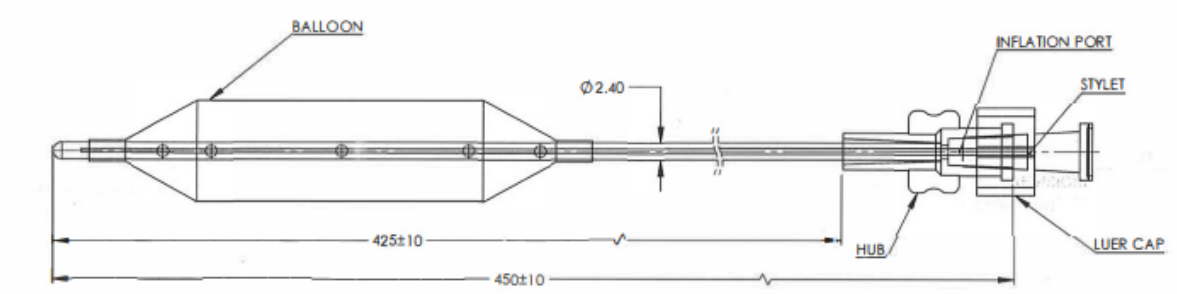
Indications for Use

METIC™ – Airway Balloon Catheter is intended to dilate strictures of the airway.

Federal law (USA) restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.

Device Description

The METIC™ – Airway Balloon Catheter is comprised of a single lumen catheter with a high pressure balloon near the distal tip. A stylet is provided to facilitate advancement of the balloon dilation catheter to the desired location. The stylet must be removed before inflation of the high pressure balloon. A Luer at the proximal end is used for the placement of the stylet and injecting sterile water into the balloon.



Mechanism of Action

Airway structures, also called airway stenosis, are an obstruction of the trachea (airway or windpipe) due to constriction or narrowing of the passageway. Airway strictures affect an individual's ability to breathe and cough up secretions in the lungs. METIC™ – Airway Balloon Catheter goes into the airway via mouth under visualization of endoscope. Balloon is deployed at the stenosis area. Once placed to the right location balloon is than inflated using saline to desired atmospheric pressure to dilate the airway. After certain second it balloon is deflated. If required multiple dilation is performed in order to achieve desired dilation of airway.

PRINCIPLE OF OPERATION

Metic™ Airway Balloon catheter operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. It has a single lumen shaft. The catheter features a balloon of appropriate compliance for the clinical application, constructed from a polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with well characterized rates of inflation and deflation and a defined burst pressure. The device generally features a type of endoscopic marker to indicate catheter position relative to the tip of guiding catheter during use.

Since the operating principles of Airway Balloon catheter and PTCA catheter are similar, the Guidance for industry & FDA staff class II special control guidance document for certain Percutaneous Transluminal coronary angioplasty (PTCA) catheters, September 8, 2010 was used for test methodology and sampling. However, the acceptance criteria are based on intended use specifications for an airway balloon and as per the predicate devices.

Technological Characteristics

Metic™ Airway Balloon Catheter Specification

<table>
<tr><th>Characteristics</th><th>Specification</th></tr>
<tr><td>Balloon Length (mm)</td><td>24 mm and 40 ± 1mm</td></tr>
<tr><td>Balloon Diameters (mm)</td><td>5.00, 7.00, 9.00, 10.00, 12.00, 14.00 & 16.00 mm ± 10% at balloon Nominal pressure</td></tr>
<tr><td>Balloon profile</td><td>
<table>
<tr><td>Balloon Size</td><td>Profile</td></tr>
<tr><td>5.0 X 24mm</td><td>2.60 to 3.00 mm</td></tr>
<tr><td>7.0 X 24mm</td><td rowspan="3">3.10 to 3.70 mm</td></tr>
<tr><td>9.0 X 24mm</td></tr>
<tr><td>10.0 X 40mm</td></tr>
<tr><td>12.0 X 40mm</td><td rowspan="3">3.80 to 4.50 mm</td></tr>
<tr><td>14.0 X 40mm</td></tr>
<tr><td>16.0 X 40mm</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Characteristics</th><th>Specification</th></tr>
<tr><td>Catheter Usable Length</td><td>425 ± 10 mm</td></tr>
<tr><td>Catheter Overall Length</td><td>450 ± 10 mm</td></tr>
<tr><td>Balloon burst test</td><td>Actual Burst Pressure:
<table>
<tr><td>Balloon Size</td><td>Burst Pressure</td></tr>
<tr><td>5.0 X 24mm</td><td rowspan="4">≥ 22 ATM</td></tr>
<tr><td>7.0 X 24mm</td></tr>
<tr><td>9.0 X 24mm</td></tr>
<tr><td>10.0 X 40mm</td></tr>
<tr><td>12.0 X 40mm</td><td rowspan="3">≥ 15 ATM</td></tr>
<tr><td>14.0 X 40mm</td></tr>
<tr><td>16.0 X 40mm</td></tr>
</table></td></tr>
<tr><td>Balloon Diameter @ Nominal Pressure (mm)</td><td>
<table>
<tr><td>Balloon Size</td><td>Nominal Pressure</td></tr>
<tr><td>5.0 X 24mm</td><td rowspan="4">10 ATM</td></tr>
<tr><td>7.0 X 24mm</td></tr>
<tr><td>9.0 X 24mm</td></tr>
<tr><td>10.0 X 40mm</td></tr>
<tr><td>12.0 X 40mm</td><td rowspan="3">7 ATM</td></tr>
<tr><td>14.0 X 40mm</td></tr>
<tr><td>16.0 X 40mm</td></tr>
</table></td></tr>
<tr><td>Balloon Fatigue Test</td><td>Catheter shall withstand 10 cycles minimum to Rated Burst Pressure
<table>
<tr><td>Balloon Size</td><td>Rated Burst Pressure</td></tr>
<tr><td>5.0 X 24mm</td><td rowspan="4">17 ATM</td></tr>
<tr><td>7.0 X 24mm</td></tr>
<tr><td>9.0 X 24mm</td></tr>
<tr><td>10.0 X 40mm</td></tr>
<tr><td>12.0 X 40mm</td><td rowspan="3">10 ATM</td></tr>
<tr><td>14.0 X 40mm</td></tr>
<tr><td>16.0 X 40mm</td></tr>
</table></td></tr>
</table>

Characteristics	Specification
Balloon inflation Time (Medium – Water)	≤ 25 seconds
Balloon Deflation	< 10 seconds
Balloon Refoldability Test	Minimum 3 pleats should appear when looked from the tip after balloon inflation & Deflation up to 10 cycles at Nominal Pressure.

Patient contacting material

Component name	***Material of Construction***	***Unique material Identifier***	***Patient Contact***
METIC™ Airway Balloon Catheter			
Balloon	Nylon 12	Vestamid care ML21	Yes
Catheter tubing	Polyether block amide	Pebax 72 D	Yes
Stylet	Stainless Steel	SS304V	No
Catheter Hub	Polycarbonate	-	No

Contact classification as per ISO 10993-1

Device Name	Category	Contact	Contact Duration
METIC™ Airway Balloon Catheter	Surface contacting	Mucosal membranes	A – Limited Exposure < 24 H

Clinical Study Results

Not applicable. Based on the substantial equivalence discussion and the testing results from bench tests, it was determined that a clinical study was not required to demonstrate substantial equivalence with the predicate devices.

Substantial Equivalence

The Metic™ Airway Balloon Catheter is substantially equivalent with the predicate devices contained in the following table.

Characteristics	Subject Device	Predicate Device		Safety / Effectiveness
Device Name	Metic™ Airway Balloon Catheter	Inspira *Air*® Balloon Dilation System **(510K no. K090660)** ***Primary Predicate***	Aeris® Balloon Dilation Catheter **(510K no. K150951)** ***Second Predicate***	-
Manufacturer	Meril Life Sciences Pvt. Ltd., India	Acclarent Inc.	Bryan Medical Inc.	-
Common Name	Airway Balloon Catheter	Airway Balloon Catheter	Balloon Dilation Catheter	Same
Class	II	II	II	Same
Product Code	KTI	KTI	KTI	Same
Regulation Number	21 CFR 874.4680	21 CFR 874.4680	21 CFR 874.4680	Same
Single Patient Use	Yes	Yes	Yes	Same
Direct Patient Contact	Yes	Yes	Yes	Same
Balloon Diameter (mm)	5.0,7.0, 9.0,10.0, 12.0,14.0,16.0	5.0,7.0, 8.5,10.0, 12.0,14.0,16.0	5.0,7.0, 8.0, 9.0,10.0, 12.0,14.0,16.0	Same
Balloon Length (mm)	24 ± 1 mm	24 ± 1 mm	30 ± 1 mm	Same
	40 ± 1 mm	40 ± 1 mm	40 ± 1 mm	

Characteristics	Subject Device	Predicate Device		Safety / Effectiveness
Maximum Inflation Pressure	10-17 ATM	8 – 16 ATM	10 & 17 ATM	Inflation pressure range is within the range of predicate device.
Flexible Shaft	Yes	Yes	Yes	Same
Indications for Use	The Metic™ Airway Balloon Catheter is an instrument intended to dilate strictures of the airway.	The Inspira AIR® Balloon Dilation System is an instrument intended to dilate strictures of the airway tree.	Aeris® Airway Balloon Dilation Catheter is intended for use in adult and pediatric populations to dilate strictures of the airway tree.	Same
Technological Characteristics	Enables dilation of airway Strictures	Enables dilation of airway Strictures	Enables dilation of airway strictures	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Same
Packaging	Thermoformed tray in pouch	Thermoformed tray in pouch	Thermoformed tray in pouch	Same
Labelled as non-pyrogenic?	No	No	No	Same
Principles of Operation	Hydraulic pressurization applied through an inflatable balloon	Hydraulic pressurization applied through an inflatable balloon	Hydraulic pressurization applied through an inflatable balloon	Same
Biocompatibility	Complies with ISO 10993	Complies with ISO 10993	Complies with ISO 10993	Same

Labelling

The Labels and IFUs of Metic™ Airway Balloon Catheter are in accordance with complies with requirements of 21 CFR 801.109 and ISO 15223 - 1: Medical Devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements.

Sterilization

Metic™ Airway Balloon Catheter is sterilized by traditional Ethylene Oxide sterilization methods as described in Sterility Review Guidance K90-1.

Method followed for Ethylene Oxide sterilization is as per ANSI /AAMI/ISO 11135 (Sterilization of health care products – Ethylene Oxide - Part 1 (Requirements for development, validation and routine control of a sterilization process for medical devices).

The Ethylene Oxide sterilization process is validated as per ANSI /AAMI/ ISO 11135-1 Sterilization of health care products – Ethylene Oxide - Part 1 (Requirements for development, validation and routine control of a sterilization process for medical devices), Method C (Overkill Method: This method is based on demonstrating that the sterilization of a microbial challenge (biological indicator) exceeds the challenge posed by the bioburden of the product. This method is commonly used to demonstrate total inactivation of a 10^6 BI at a half-cycle exposure time. When exposure time is doubled, a minimum 12 SLR is delivered during EO exposure).

SAL = 10^{-6}

Ethylene Oxide residuals remaining on the device is in accordance with ISO 10993-7: Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals" for ethylene oxide and ethylene chlorohydrin

The maximum residual levels after EO sterilization are as under.

1. Ethylene Oxide < 4mg/device
2. Ethylene Chlorhydrin < 9mg/device

Packaging

Metic™ Airway Balloon Catheter is supplied sterile. The components are packed in below packaging configuration. The Sterile barrier packaging is designed to maintain sterility and permit fast and easy opening in a single peel.

Metic™ Airway Balloon Catheter is available as an integrated System.

Packaging Configuration

S. N.	Component	Sterile barrier	Secondary Packaging
1.	Metic™ Airway Balloon Catheter	Thermoformed tray sealed with Tyvek lid	Cardboard carton along with “Instruction for use”

Shelf-life

The proposed shelf life of Metic™ Airway Balloon Catheter is 5 years. The shelf life study for Metic™ Airway Balloon Catheter was planned as per ASTM 1980 recommended conditions. The study was conducted with elevated temperature condition and with real time conditions. As per ASTM 1980 following conditions were used to establish the shelf life of the Metic™ Airway Balloon Catheter.

The real time shelf time study for 2 years has been completed. The result of elevated temperature and real-time study has not shown any significant changes in product characteristics.

Test Conditions

Study	Storage Conditions	Time period
Metic™ Airway Balloon Catheter		
Accelerated	40 ± 2°C / 75 ± 5 % RH	457 days
Long term	30 ± 2°C / 65 ± 5 % RH	60 months

Biocompatibility study

Biological evaluation of Metic™ Airway Balloon Catheter as per Use of International Standard ISO 10993-1 ("Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". (September 8, 2023). Guidance for Industry and Food and Drug Administration Staff)

Performance

Since the operating principles of Airway Balloon catheter and PTCA catheter are similar, the Guidance for industry & FDA staff class II special control guidance document for certain Percutaneous Transluminal coronary angioplasty (PTCA) catheters, September 8, 2010 was used for test methodology and sampling. However, the acceptance criteria were based on the intended use specifications for an airway balloon and as per the predicate devices.

The safety and effectiveness of METIC™ – Airway Balloon Catheter has been evaluated for the following performance and safety requirements:

- Visual Inspection
- Dimensional Measurement
- Balloon Burst and Balloon Compliance
- Inflation and Deflation Time
- Catheter Bond Strength
- Flexibility and Kink
- Torquability
- Catheter Fatigue
- Balloon Hub Measurement
- Proximal Luer fitting
- Balloon Preparation, Deployment and Retraction

Conclusion

The performance, biocompatibility, sterilization, packaging and shelf life study conducted on METIC™ – Airway Balloon Catheter demonstrated the device is as safe and as effective as the predicate device.

Hence, METIC™ – Airway Balloon Catheter is substantially equivalent to currently marketed devices having the same intended use and similar materials and performance and will perform as intended in the specified use conditions.

Compliance with Voluntary Standards

The Metic™ Airway Balloon Catheter comply with the following standards:

- ISO 14971: 2019, Medical devices - Application of risk management to medical devices.
- ISO 11607-1:2020, Packaging for terminally Sterilized Medical Devices – Part 1: Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- ISO 11135: 2014, Sterilization of Health-Care Products - Ethylene Oxide - Requirements for the Development, Validation and Routine Control of Sterilization Process for Medical Devices. Second Edition, 2014-07-09
- ISO 10993-1: 2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. 2014-07-09
- ISO 10993-7 Second Edition 2008-10-15, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
- AAMI / ANSI / ISO 10993-5:2009/(R) 2014, Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Fifth Edition 2021, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.