December 9, 2021

DISA Medinotec
% Matthew Krueger
Senior Consultant
Biologics Consulting Group, Inc.
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K211894
Trade/Device Name: Trachealator
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: KTI

Dear Matthew Krueger:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 11/24/2021. Specifically, FDA is updating this SE Letter for a typo in the Sponsor name, from "DISA Medintec" to "DISA Medinotec" as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shu-Chen Peng, Ph.D., OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6481, shu-chen.peng@fda.hhs.gov.

Sincerely,

Shuchen Peng -S

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

November 24, 2021

DISA Medintec
% Matthew Krueger
Senior Consultant
Biologics Consulting Group, Inc.
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K211894
Trade/Device Name: Trachealator
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: October 27, 2021
Received: October 28, 2021

Dear Matthew Krueger:

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,

Shuchen Peng -S

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

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the D35 Airway Dilation Catheter (Trachealator) is provided below.

1. SUBMITTER

Applicant:	DISA Medinotec Stand 171, Northlands Business Park, Bush Telegraph Street, Northriding, Johannesburg, 2169, South Africa +27 (0) 87 330 2301
Contact:	Michelle Nieuwoudt Quality & Regulatory Affairs Manager DISA Medinotec +27 (0) 87 330 2301 michelle@disals.co.za
Submission Correspondent:	Matthew Krueger Senior Consultant Biologics Consulting Group, Inc. 1555 King Street, Suite 300 Alexandria, VA 22314 571-777-9548 mkrueger@biologicsconsulting.com
Date Prepared:	October 26, 2021

2. DEVICE

Device Trade Name:	Trachealator
Device Common Name:	D35 Airway Dilation Catheter
Classification Name	21CFR 874.4680, Bronchoscope (flexible or rigid) and accessories
Regulatory Class:	Class II
Product Code:	KTI

3. PREDICATE DEVICE

Predicate Device:	K170759 – CRE Pulmonary Balloon Dilatation Catheter (Boston Scientific)
Reference Device:	K110218 – Inspira AIR Balloon Dilation System (Acclarent, Inc.)

4. DEVICE DESCRIPTION

The D35 Airway Dilation Catheter (marketing name: Trachealator) is a sterile single-use device used during airway dilatation procedures.

The proposed device consists of a series of parallel balloons on a catheter which, when deployed, provides an outward radial force while also creating an inter balloon space or passage for airflow. Thus, airway occlusion is avoided.

The D35 Airway Dilation Catheter is also packaged with a double-ended PTFE-coated stainless-steel guidewire. The guidewire consists of a two-tip configuration with a length of 1500 mm. One end has a straight tip configuration, while the other end consists of a J-tip with a 6 mm diameter. The catheter is also used with an inflation device that is not provided with the catheter.

The D35 Airway Dilation Catheter is provided in nine models. The only differences between the models are the balloon length and diameter. Refer to Table 1 for the specifications for each of the 9 models.

Table 1: Catheter Models and Balloon Specifications

Product Reference Number	Balloon Length (mm)	Balloon Diameter (mm)	Nominal Pressure (atm)	Maximum Pressure (atm)
TRD1-06030	30	6.0	6	12
TRD1-07030	30	7.0	6	12
TRD1-08030	30	8.0	6	12
TRD1-09030	30	9.0	6	12
TRD1-10030	30	10.0	6	12
TRD1-12040	40	12.0	6	12
TRD1-14540	40	14.5	6	12
TRD1-16040	40	16.0	6	12
TRD1-18040	40	18.0	6	12

5. INTENDED USE/INDICATIONS FOR USE

The device is indicated for use in dilatation techniques to open or expand stenosis in the airway.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Predicate Device Indications for Use

K170759 – Boston Scientific CRE Pulmonary Balloon Dilatation Catheter

The CRE Pulmonary Balloon Dilatation Catheter is intended to be used endoscopically to dilate strictures of the airway tree.

Subject Device Indications for Use

The Trachealator is indicated for use in dilatation techniques to open or expand stenosis in the airway.

The intended use of the Trachealator (internal device name: D35 Airway Dilation Catheter) is the same as that of the predicate Boston Scientific CRE Pulmonary Balloon Dilation Catheter. The proposed Indications for Use statement is similar to the predicate IFU but uses slightly different wording. Despite the difference in wording, both Indications for Use statements convey the same clinical use of the device.

Technological Comparisons

The table below compares the key technological feature of the subject device to the predicate device (CRE Pulmonary Balloon Dilatation Catheter-Boston Scientific [K170759]) and the reference device (Inspira AIR Balloon Dilation System-Acclarent, Inc. [K110218]). The reference device is used because the Inspira device helps to better define the "box" of device attributes that are cleared to demonstrate that the Trachealator's key parameters fall within the range of cleared devices.

Table 2: Technological Comparison

	Proposed Device	Predicate Device	Reference Device	Comments on Similarities/Differences
510(k) Number	TBD	K170759	K110218	—
Applicant	DISA Medinotec	Boston Scientific	Acclarent	—
Device Name	D35 Airway Dilation Catheter (Trachealator)	CRE Pulmonary Balloon Dilation Catheter	Inspira AIR Ball0on System	—
Classification Regulation	21 CFR 874.4680	21 CFR 874.4680	21 CFR 874.4680	Identical
Product Code	KTI	KTI	KTI	Identical
Indications for Use	Indicated for use in dilatation techniques to open or expand stenosis in the airway.	Intended to be used endoscopically to dilate strictures of the airway tree.	Intended to dilate strictures of the airway tree.	Equivalent

	Proposed Device	Predicate Device	Reference Device	Comments on Similarities/Differences
Guidewire/Stylet lumen	Yes	Yes	Yes	**Identical**
Packaged with Guidewire or Stylet	Guidewire	None	Stylet	**Equivalent**
Guidewire/Stylet Diameter	Guidewire 0.018" (6 – 12 mm) 0.035" (14.5 – 18 mm)	Guidewire ≤ 0.035" (0.89 mm)	Stylet 0.84 mm (tip)*	**Equivalent** This difference in diameter does not significantly alter performance, as 0.018" is also a standard guidewire size used in hospitals, and the wire is supplied as an accessory with the Trachealator.
Strain relief	Yes	Yes	Yes	**Identical**
Usable Catheter Length (mm)	650 ± 10 mm	1100 mm	450 mm	**Equivalent** The Trachealator has a usable catheter length similar to other devices on the market.
Outer Lumen Catheter Diameter (mm)	3.0 ± 0.05 (6 – 10 mm clusters) 3.5 ± 0.05 (12 – 18 mm clusters)	2.5 mm	2.15 mm (14x40)* 2.7 mm (16x40)*	**Equivalent** This small difference in diameter does not affect its performance.
Inflated Balloon Cluster/ Balloon Shape	Six/eight cylindrical balloons, arranged in parallel in a circular configuration, and bonded together at their contact points	Straight body with spherical ends	Straight body with conical end	**Equivalent** The Trachealator balloon is made of 6 or 8 smaller cylindrical balloons arranged in a circular configuration designed to create a center channel, which the other devices do not have. All three balloons dilate an airway in a radial manner; therefore, their function is the same.
Effective Balloon Length (mm) (Balloon Diameter, (mm))	27 (6 – 10 mm diameter clusters) 37 (12 – 18 mm diameter clusters)	30 (8 – 12) 55 (12 – 18)	24 (5, 7, 8.5) 40 (10,12,14,16)	**Equivalent** Small differences in balloon lengths exist, but the subject device lengths are within the range of lengths for the cleared predicate and reference devices.
Capable Balloon Diameter (mm)	Diameters ranging from 6 to 18 mm	8-9-10 10-11-12 12-13.5-15 15-16.5-18 18-19-20	5, 7, 8.5,10, 12, 14,16, 18	**Equivalent** The Trachaelator sizes (diameters) are within the range of other cleared devices.

	Proposed Device	Predicate Device	Reference Device	Comments on Similarities/Differences
Markers	1 x Radiopaque 1 x Visual marker	2 x Radiopaque	No markers	**Equivalent** The predicate and subject device both provide markers to assist in visualization of balloon.
Nominal pressure: atm (balloon OD mm)	6 atm (6 – 18)	3 atm	Only Maximum Pressure Given	**Equivalent** Pressure at which nominal diameter is achieved differs. Higher pressures provide a greater ability to dilate a lesion, but the principle is similar.
Rated Burst Pressure / Maximum Pressure (Balloon OD mm)	12 atm (6 - 18)	Balloon Length 55 mm: 6 atm (18-19-20) 7 atm (15-16.5-18) 8 atm (12-13.5-15) Balloon Length 30 mm: 8 atm (10-11-12;12-13.5-15) 9 atm (8-9-10)	Balloon Length 24 mm: 16 atm (5 - 7) 12 atm (8.5) Balloon Length 40 mm: 12 atm (10) 10 atm (12 – 14) 8 atm 16)	**Equivalent** The subject device has a higher burst pressure rating than the predicate device. However, the maximum burst pressure rating is within the burst pressure rating of the reference device.
Balloon Compliance	Semi-compliant	Semi-Compliant	Non-compliant	**Identical**
Maximum Deflation Time (seconds)	2-17	10 – 30	≤ 15 & 25	**Equivalent** The Trachealator provides an improved deflation time compared to the predicate device, which is an improvement.
Capable Bronchoscope Diameter	Minimum working channel of 5 mm	2.8 mm	The balloon dilation system can be used side by side with a bronchoscope. Compatibility for use within the working channel of a bronchoscope has not been established.	**Equivalent** The functionality of the subject device is similar to the predicate device and does not raise any new questions of safety and effectiveness.
Soft Tip	Yes	Yes	No*	**Equivalent**
Shaft Design	Coaxial Lumen	Coaxial Lumen	Coaxial Lumen	**Identical**

As shown in the table above, the fundamental design and technology of the Trachealator is equivalent or identical to the predicate CRE Pulmonary Balloon and/or the reference Inspira AIR Balloon. The minor differences between the subject device and predicate device does not raise questions of safety and effectiveness. Performance testing supports substantial equivalence, that the subject device performs as intended and that the subject device meets the device specifications.

7. PERFORMANCE DATA

Biocompatibility Testing

The balloons and the outer shaft are direct patient contacting devices classified as a surface device, in contact with tissue, with limited contact duration (≤24h) based on the intended use. Other parts of the catheter (inner lumen shaft and tip, radiopaque marker, film on the inner surface of the balloon cluster, and adhesive bonds and the guidewire provided with the device, may be positioned in the patient's airway and therefore encounter blood, mucous, or phlegm and thereby indirectly contact patient's tissues. These are an indirect patient contacting device classified as a surface device, in contact with tissue, with limited contact duration (≤24h).

Biocompatibility testing (cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, and pyrogenicity) was performed in accordance with the following standards:

ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

ISO 10993-11:2018, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

ISO 10993-12:2012, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

The D35 Airway Dilation Catheter passed all biocompatibility testing.

Sterilization and Shelf Life

The device is EO sterilization, validated by a half cycle / over-kill approach in accordance with ISO 11135:2014. The sterility assurance level is 10^{-6}. The D35 Airway Dilation Catheters have been verified according to ISO 10993-7:2008 "Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals". Shelf-life testing was conducted to support a 3 year shelf life. Packaging was tested for seal strength and dye leak.

Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. It contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software Verification and Validation Testing

Not applicable. The device contains no software.

Bench Testing

The following performance testing supports substantial equivalence, that the D35 Airway Dilation Catheters performs as intended and that the catheter's meets their device specifications:

- Visual inspection and dimensional verification

- Force to remove balloon protector
- Crossing diameter
- Simulated use
- Friction on the guide wire
- Visibility/radiopacity
- Compliance and nominal length
- Inflation/deflation times
- Rated fatigue pressure
- Rated burst pressure
- Bond strength
- Catheter flexibility
- Catheter kink
- Torque strength
- Air leak
- Liquid leak
- Cluster crushing
- Radial strength
- Dilation force
- Tip perforation
- High tensile load balloon deflation
- Inter balloon area verification

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSION

Based on the detailed comparison to the predicate device and the performance testing, the D35 Airway Dilation Catheter can be found substantially equivalent to the predicate device.

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)*
K211894

Device Name
Trachealator

Indications for Use *(Describe)*
The Trachealator is indicated for use in dilatation techniques to open or expand stenosis in 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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