



October 29, 2024

Novatech SA  
Stuart K. Montgomery  
President Boston Medical Products, Inc.  
Z.I. Athélia III -1058, Voie Antiope  
La Ciotat CEDEX, 13705  
France

Re: K243126  
Trade/Device Name: Tracheobronxane™ Dumon®  
Regulation Number: 21 CFR 878.3720  
Regulation Name: Tracheal Prosthesis  
Regulatory Class: Class II  
Product Code: NWA  
Dated: September 19, 2024  
Received: September 30, 2024

Dear Stuart K. Montgomery:

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.

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](mailto: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

Submission Number (if known)

Device Name

TRACHEOBRONXANE™ DUMON®

Indications for Use (Describe)

For maintaining open the airway, after dilation of the stenosis or resection of the obstruction, in particular in case of:

- Tracheobronchial tumors
- Tracheal stenoses with scarring
- Stenoses following surgical anastomosis, resection or pulmonary transplantation

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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Record's title

**TRACHEOBRONXANE™ DUMON® 510(k) Summary**

# **TRACHEOBRONXANE™ DUMON®**

## **510(k) Summary**

**NOVATECH SA  
Z.I. Athélia III – 1058, Voie Antiope  
13705 La Ciotat CEDEX  
FRANCE**



Record's title

**TRACHEOBRONXANE™ DUMON® 510(k) Summary**

## **1 Submitter**

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NOVATECH SA  
Z.I. Athélia III – 1058, Voie Antiope  
13705 La Ciotat CEDEX  
FRANCE

### **Contact Person**

Stuart K. Montgomery  
President  
Boston Medical Products Inc.  
70 Chestnut Street  
Shrewsbury, MA  
01545, USA  
Ph: 508-898-9300 ext. 240  
Fax: 508-898-2373

### **Date Prepared**

September 19, 2024

## **2 Device**

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Device Name:	TRACHEOBRONXANE™ DUMON®
Regulation Number and Description:	878.3720 Tracheal Prosthesis
Medical Specialty	GENERAL AND PLASTIC SURGERY DEVICES
Product Code:	NWA
Device Class:	2

## **3 Predicate Device**

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Device Name:	ENDOXANE®
Original Applicant:	NOVATECH SA
510(k) Number:	K971509
Regulation Number:	878.3720 Tracheal Prosthesis
Product Code:	NWA
Device Class:	2

	Record's title
	<b>TRACHEOBRONXANE™ DUMON® 510(k) Summary</b>

#### **4 Device Description**

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The TRACHEOBRONXANE™ DUMON® stents are flexible tracheobronchial tubes made of medical grade silicone, designed to improve patient respiration capacity while acting as trachea or bronchi support. These medical devices are designed to conform to individual anatomies.

Each stent has a specific treatment, to improve the evacuation of mucus in order to limit the risk of obstruction.

A large range of shape, thickness and sizes is available depending on the pathology to be treated, patient intrinsic factor and location of the implantation. Indeed, the TRACHEOBRONXANE™ DUMON® range consists of various models which vary from each other in the following characteristics:

- The stents type: TD, TF, BD, Y, ST corresponding to various profiles made of silicone with different hardness;
- The dimensions: each profile consists of different sizes in diameter and length;
- The radiopacity: stents can be provided radiopaque or not radiopaque; barium sulfate is added during the manufacturing process in order to make the stent radiopaque which allows obtaining a better visibility by X-rays radiography.

The TRACHEOBRONXANE™ DUMON® stents have been designed with studs in order to facilitate their anchorage in the trachea or bronchi (on cartilage rings). The number of stud rows is depending on the stent profile and stent final destination (bronchi or trachea).

The TRACHEOBRONXANE™ DUMON® stent holds the respiratory tract open by exerting a radial force.

#### **5 Intended Use**

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For maintaining open the airway, after dilation of the stenosis or resection of the obstruction, in particular in case of:

- Tracheobronchial tumors
- Tracheal stenoses with scarring
- Stenoses following surgical anastomosis, resection or pulmonary transplantation.

	Record's title
	<b>TRACHEOBRONXANE™ DUMON® 510(k) Summary</b>

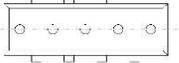
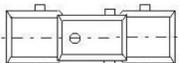
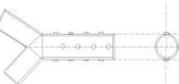
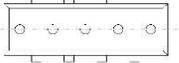
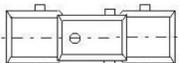
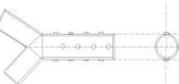
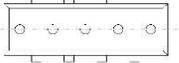
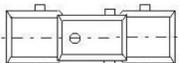
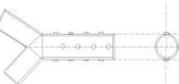
## 6 Comparison of technological characteristics with predicate device

**Table 1: Side-by-Side Comparison of TRACHEOBRONXANE™ DUMON® with the Predicate Device**

<b>Item</b>	<b>Proposed Device: TRACHEOBRONXANE™ DUMON®</b>	<b>Predicate Device: ENDOXANE®</b>
<b>510k</b>		K971509
<b>Product Code</b>	NWA	same
<b>Regulation Number</b>	878.3720 - Tracheal prosthesis	same
<b>Class</b>	2	same
<b>Intended Use</b>	The product is intended for use in the trachea and/or bronchus to keep the airway open The product is for long-term use.	same
<b>Indication for Use</b>	For maintaining open the airway, after dilation of the stenosis or resection of the obstruction, in particular in case of: <ul style="list-style-type: none"> <li>• Tracheobronchial tumors</li> <li>• Tracheal stenoses with scarring</li> <li>• Stenoses following surgical anastomosis, resection or pulmonary transplantation</li> </ul>	same
<b>Patient Target Group</b>	<ul style="list-style-type: none"> <li>• Infants and young children</li> <li>• Children and young people</li> <li>• Adults</li> <li>• Patients of any gender</li> </ul>	same
<b>Intended User</b>	Physician	same
<b>Anatomical Sites</b>	trachea and/or bronchus	same
<b>Environment of Use</b>	<ul style="list-style-type: none"> <li>• Operating room <i>controlled area with access restrictions, strict hygiene concept, controlled airflow and ideal illumination; product to be used under sterile conditions only</i></li> <li>• Treatment room <i>operating room with lesser requirements but has controlled hygiene concept; product may be used under sterile or non-sterile conditions</i></li> <li>• Endoscopy suite</li> </ul>	same
<b>Energy used and / or delivered</b>	No energy is used for this device	same

	Record's title
	<b>TRACHEOBRONXANE™ DUMON® 510(k) Summary</b>

**Table 1: Side-by-Side Comparison of TRACHEOBRONXANE™ DUMON® with the Predicate Device**

<b>Item</b>	<b>Proposed Device: TRACHEOBRONXANE™ DUMON®</b>	<b>Predicate Device: ENDOXANE®</b>										
<b>Design</b>	<table border="1"> <thead> <tr> <th><b>Stent profile</b></th> <th><b>Scheme</b></th> </tr> </thead> <tbody> <tr> <td>TRACHEOBRONXANE™ DUMON® BD Bronchial Stent</td> <td rowspan="3">  </td> </tr> <tr> <td>TRACHEOBRONXANE™ DUMON® TD Tracheal Stent</td> </tr> <tr> <td>TRACHEOBRONXANE™ DUMON® TF Thin Tracheal Stent</td> </tr> <tr> <td>TRACHEOBRONXANE™ DUMON® ST Hourglass Stent</td> <td>  </td> </tr> <tr> <td>TRACHEOBRONXANE™ DUMON® Y Bifurcation Stent</td> <td>  </td> </tr> </tbody> </table>	<b>Stent profile</b>	<b>Scheme</b>	TRACHEOBRONXANE™ DUMON® BD Bronchial Stent		TRACHEOBRONXANE™ DUMON® TD Tracheal Stent	TRACHEOBRONXANE™ DUMON® TF Thin Tracheal Stent	TRACHEOBRONXANE™ DUMON® ST Hourglass Stent		TRACHEOBRONXANE™ DUMON® Y Bifurcation Stent		Same, additionally TRACHEOBRONXANE™ DUMON® BB - Ultra Thin Stent
	<b>Stent profile</b>	<b>Scheme</b>										
	TRACHEOBRONXANE™ DUMON® BD Bronchial Stent											
	TRACHEOBRONXANE™ DUMON® TD Tracheal Stent											
	TRACHEOBRONXANE™ DUMON® TF Thin Tracheal Stent											
	TRACHEOBRONXANE™ DUMON® ST Hourglass Stent											
TRACHEOBRONXANE™ DUMON® Y Bifurcation Stent												
<b>Materials</b>	medical grade silicone, barium sulfate	same										
<b>Principles of Operation</b>	Manually operable	same										
<b>Sterilization</b>	Supplied sterile	Supplied non-sterile										
<b>Shelf-Life</b>	3 years	5 years										
<b>Chemical Safety</b>	No hazardous substances	same										
<b>Compatibility with environment and other devices</b>	The manufacturer recommends using a delivery system type TONN™ / NOVATECH	same										
<b>Mechanical Safety</b>	Visual examination, weighing test, compression test and elongation test has been performed on TRACHEOBRONXANE™ DUMON® stents. Additionally, a fatigue test simulated the normal usage of the stents has been performed.	same										

	Record's title
	<b>TRACHEOBRONXANE™ DUMON® 510(k) Summary</b>

## 7 Performance Data

### Biocompatibility Testing

According to its intended purpose and ISO 10993-1, TRACHEOBRONXANE™ DUMON® is categorized as:

Category	Contact	Contact duration
Implant medical device	Tissue	C-Long term (>30 days)

**Table 1: Side-by-Side Comparison of TRACHEOBRONXANE™ DUMON® with the Predicate Device**

TRACHEOBRONXANE™ DUMON®	ENDOXANE®
<b>Applicable standard:</b> ISO 10993-1	same
<p><b>Chemical characterization</b>            Chemical <b>characterization</b> of final products, manufacturing process, packaging, sterilization, and storage revealed no risk of adverse effects on the patient.            Chemical <b>testing</b> and subsequent risk mitigating assessment revealed no risk of systemic toxic effects.            Therefore, the biological effects as follows can be excluded:</p> <ul style="list-style-type: none"> <li>• systemic toxicity</li> <li>• systemic implantation effects</li> <li>• genotoxicity</li> <li>• carcinogenicity</li> <li>• reproductive and developmental toxicity</li> <li>• toxicokinetics</li> </ul>	same
<p><b>Cytotoxicity</b>            in-vitro studies on NuSil medical-grade silicones passed.            in-vitro studies on DUMON® final stents passed.</p>	same
<p><b>Sensitization and irritation</b>            Chemical testing did not reveal sensitizing substances.            In-vivo studies on NuSil medical-grade silicones passed.            Long history of safe clinical use.</p>	same
<p><b>Irritation</b>            Chemical testing did not reveal irritating substances.            In-vivo studies on NuSil medical-grade silicones passed.            Long history of safe clinical use.</p>	same
<p><b>Material-mediated pyrogenicity</b>            The devices do not contain any of the substances listed in DIN EN ISO 10993-11:2018, Annex G, and are not made of biologically-derived materials.            In-vivo studies on NuSil medical-grade silicones revealed no risk for material-mediated pyrogenicity.            Long history of safe clinical use.</p>	same



Record's title
<b>TRACHEOBRONXANE™ DUMON® 510(k) Summary</b>

TRACHEOBRONXANE™ DUMON®	ENDOXANE®
<p><b>Systemic toxicity (acute, subacute, subchronic, chronic)</b>            See chemical characterization.            In-vivo studies on NuSil medical-grade silicones passed.            Long history of safe clinical use.</p>	same
<p><b>Implantation effects</b>            See chemical characterization.            In-vivo studies on NuSil medical-grade silicones passed.            Atraumatic design without sharp edges.            Removal of device after 12 months recommended.            Long history of safe clinical use.</p>	same
<p><b>Genotoxicity</b>            See chemical characterization.            In-vitro studies on NuSil medical-grade silicones passed.</p>	same
<p><b>Carcinogenicity</b>            See chemical characterization.            Long history of safe clinical use and extensive clinical data.</p>	same
<p><b>Reproductive and developmental toxicity</b>            See chemical characterization.            Long history of safe clinical use.</p>	same
<p><b>Degradation</b>            Due to the non-polar nature of silicone (body contacting material) no degradation is expected in physiological surrounding.            Chemical testing on DUMON® stents revealed no degradation products.            Conducted shelf-life tests gave no hint for degradation of material.            Long history of safe clinical use.</p>	same
<p><b>Toxicokinetics</b>            Chemical testing on DUMON® stents revealed no substances in toxicologically relevant amounts.</p>	same
<p><b>Conclusion:</b>            No adverse biological effects expected.</p>	<p><b>Conclusion:</b>            No adverse biological effects expected.</p>

According to the available biological information and experimental data, and supported by the long history of safe use of TRACHEOBRONXANE™ DUMON® there is no reason to doubt the biological suitability of this device.



Record's title

**TRACHEOBRONXANE™ DUMON® 510(k) Summary**

### **Benchmark Performance Tests**

Several performance tests on TRACHEOBRONXANE™ DUMON® stents have been carried out to analyze the device characteristics.

The following tests demonstrate the technical equivalence of aged stents with new manufactured products.

### **Fatigue**

Specific test procedures were performed on brand new stents and stents, which were stressed by fatigue test. This fatigue test simulated the normal usage of the stents. The gathered data of stressed and unstressed stents were compared. Additionally, stents were stored unstressed in a water bath to investigate the influence of the water bath in comparison to the influence of the fatigue test.

### **Weighing**

A weighing test was conducted on the stents to assess the absorption or disposal on substances out of or into the stent.

The weighing test was performed on the stents treated in the water bath and treated in the fatigue test.

### **Compression**

The compression test examines the radial performance of the stents.

Stents from fatigue test are compressed with the use of a defined compression stamp to examine the force required to compress the stents.

## **8 Shelf Life/Sterilization**

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**Method of Sterilization:** Steam Sterilization

**Shelf-Life:** 3 years

## **9 Conclusion**

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The subject device TRACHEOBRONXANE™ DUMON® is substantially equivalent to predicate device, ENDOXANE®.

ENDOXANE® is the submitter's own legally marketed predicate device.

The only difference between the products is TRACHEOBRONXANE™ DUMON® is supplied sterile and ENDOXANE® is supplied non-sterile.

The indications for use and materials of construction remain unchanged between the subject device and the manufacturer's existing device.