February 6, 2025

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

Re: K242324
Trade/Device Name: DUTAU-NOVATECH®
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: January 8, 2025
Received: January 8, 2025

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) 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242324

Device Name
DUTAU-NOVATECH®

Indications for Use *(Describe)*
The DUTAU-NOVATECH® is intended for rigid bronchoscopy.
For use in trachea and bronchi. To be used by qualified surgeons during ENT endoscopic procedures.
The DUTAU-NOVATECH® is suitable for use for a patient population greater than 5 years of age.

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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DUTAU-NOVATECH®

510(k) Summary

NOVATECH SA

Z.I. Athélia III – 1058, Voie Antiope

13705 La Ciotat CEDEX

FRANCE

1 Submitter

NOVATECH SA

Z.I. Athélia III – 1058, Voie Antiope

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Contact Person

Stuart K. Montgomery

President

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01545, USA

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Date Prepared

October 29, 2024

2 Device

Device Name:	**DUTAU-NOVATECH®**
Regulation Number and Description:	874.4680 Bronchoscope (flexible or rigid) and accessories
Medical Specialty	Ear Nose & Throat
Product Code:	EOQ
Device Class:	2

3 Predicate Device

Device Name:	Karl Storz Bronchoscope Accessories
Original Applicant:	Karl Stroz Endoscopy – America, Inc.
510(k) Number:	K943700
Product Code:	EOQ
Regulation Number:	874.4680 Bronchoscope (flexible or rigid) and accessories
Device Class:	2

4 Device Description

DUTAU-NOVATECH® is a rigid bronchoscope that consists of a bronchoscope head and replaceable tubes and is fully dismantlable. It is made of medical grade stainless steel.

The tracheal tube mounted on the bronchoscope head is inserted into the trachea. The bronchial tube mounted on the bronchoscope head is inserted through the trachea into the bronchi.

A telescope and instruments for diagnosis and treatment can be inserted through these tubes into the bronchi (bronchial tube) or the trachea, respectively. To ventilate the patient, the ventilation tube can be connected either to the bronchoscope head or directly to the respective tube.

The tubes are colour coded depending on the size and have a scale to measure stenosis.

DUTAU-NOVATECH® is supplied unsterile and must be cleaned, disinfected, and sterilized prior to its use.

5 Intended Use

The DUTAU-NOVATECH® is intended for rigid bronchoscopy.

For use in trachea and bronchi.

6 Indication for Use

The DUTAU-NOVATECH® is intended for rigid bronchoscopy. For use in trachea and bronchi. To be used by qualified surgeons during ENT endoscopic procedures. The DUTAU-NOVATECH® is suitable for use for a patient population greater than 5 years of age.

7 Comparison of technological characteristics with predicate device

The DUTAU-NOVATECH® has the same operating principle and incorporates the same basic design as the predicate device, Karl Storz Bronchoscope Accessories. A summary of the technological characteristics of DUTAU-NOVATECH® compared to Karl Storz Bronchoscope Accessories is provided below:

Table 1: Side-by-Side Comparison of DUTAU-NOVATECH® with the Predicate Device

Item	Proposed Device: DUTAU-NOVATECH®	Predicate Device: Karl Storz Bronchoscope Accessories
510k		K943700
Product Code	EOQ	Same
Regulation Number	874.4680	Same
Class	II	Same
Intended Use	The DUTAU-NOVATECH® is intended for rigid bronchoscopy. For use in trachea and bronchi.	Intended to be used during endoscopic ENT procedures
Indication for Use	The DUTAU-NOVATECH® is intended for rigid bronchoscopy. For use in trachea and bronchi. To be used by qualified surgeons during ENT endoscopic procedures.	to aid the surgeon in removing fluid, tissue and foreign bodies, and inducing

Table 1: Side-by-Side Comparison of DUTAU-NOVATECH® with the Predicate Device

Item	Proposed Device: DUTAU-NOVATECH®	Predicate Device: Karl Storz Bronchoscope Accessories
	The DUTAU-NOVATECH® is suitable for use for a patient population greater than 5 years of age.	hemostasis during endoscopic ENT surgery.
Patient Target Group	- Children greater than 5 years of age and young people - Adults - Patients of all genders	Population who requires endoscopic ENT procedures to be conducted.
Intended User	To be used by qualified surgeon during ENT endoscopic procedures	Same
Anatomical Sites	to be introduced into the trachea or bronchi.	Same
Environment of Use	- Operating theatre - Treatment room - Endoscopic procedure room	Hospital
Energy used and / or delivered	No energy is used for this device	Same
Design	***Bronchial Tube/Tracheal Tube*** Lengths 25 or 35 cm, Diameters (both inner and outer) from 8.5-14 mm	***Bronchoscope Tubes*** Lengths ranging from 20-43 cm, Diameters from 3.5- 13.6 mm
	Bronchoscope head Ventilation element with Axial Retainer and Axial Cap Lateral Double Port with Lateral Caps Injection Cannula	***Caps and Telescope Guides*** Seals end of tube for viewing, allows for instrumentation
Photo of product ready for use		
Materials	Stainless steel, surgical quality; caps: silicone	Same
Principles of Operation	Manually operable	Same
Sterilization	Supplied non-sterile and reprocessed	Same
Shelf-Life	N/A	Same
Chemical Safety	No Hazardous substances	Same
Compatibility with environment and other devices	Medical devices for diagnosis and therapy intended for use in rigid bronchoscopy and compatible with the length and diameter of the respective tube	N/A
Mechanical Safety	Mechanical testing demonstrates device is strong enough to retain its integrity	Same

8 Performance Data

Biocompatibility Testing

DUTAU-NOVATECH® is an externally communicating: tissue/bone/dentin device and has contact for a limited time (<24 hours).

Table 2 provides an overall summary of the biological assessment for the the DUTAU-NOVATECH® components with body contact.

Table 1: Side-by-Side Comparison of DUTAU-NOVATECH® with the Predicate Device

bronchial / tracheal tubes	**bronchoscope head with all adaptable parts and connectors**
Nature of body contact: externally communicating with direct patient contact	**Nature of body contact**: Indirect patient contact via gas pathways (ventilation)
Applicable standard: ISO 10993-1	**Applicable standard**: ISO 18562
Chemical characterization • Standard surgical instrument steels in compliance with ASTM F899 and EN 10088 • no toxicity according to literature • no E&L expected • no degradation products expected (corrosion resistant) • absence of residues from manufacturing and packaging (validated final cleaning)	• Standard surgical instrument steels in compliance with ASTM F899 and EN 10088 • no toxicity according to literature • no chemical reaction with air or water expected • no degradation products expected (corrosion resistant) • absence of residues from manufacturing and packaging (validated final cleaning) • short contact duration • no further testing deemed necessary
Cytotoxicity • Stainless steels are not known to be cytotoxic. • *in-vitro* cytotoxicity test with reference device passed	
Sensitization and irritation • Stainless steels are not known to be sensitizing or irritating due to high corrosion resistance. • Short contact duration. Therefore, low probability of eliciting sensitization or irritation. • *in-vivo* tests with reference device passed (Guinea Pig Maximization Test; Intracutaneous irritation Test with rabbits)	
Material-mediated pyrogenicity • Device does not contain any of the substances listed in DIN EN ISO 10993-11 Annex G and is not made of biologically derived materials.	
Acute systemic toxicity • See chemical characterization • No leaching of chemical substances through the passivating oxide layer of stainless steels expected. • *in-vivo* tests with reference device passed (Acute systemic toxicity test with mice)	

bronchial / tracheal tubes	**bronchoscope head with all adaptable parts and connectors**
Conclusion: No adverse biological effects expected.	**Conclusion:** No adverse biological effects expected.

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

Benchmark Performance Tests

To verify the disconnect stability and safety for all relevant connectors of the DUTAU-NOVATECH® bronchoscope, tension test based on ISO 5356-1 have been carried out. The test results have been checked against the requirements stated in the relevant standard or against the performance of the predicate device.

An assembling test was carried out under internal protocol. The devices were assembled without conspicuousness. A visual inspection was performed after assembling the device. The requirements are fulfilled for all the test samples. There are no damages or breakages on the DUTAU-NOVATECH®.

The compression and tensile test were passed as well, no damage of the bronchoscope tubes were observed. All tubes reached the maximum test force without any conspicuities. The test was carried out under internal protocol.

The connection stability tests were passed as well. No damage or disconnection of the tube and the snap fit connection below the defined compression load and tensile load was observed. The test was carried out under internal protocol. The plug-in connection test between bronchoscope head and injection cannula or lateral double port was passed as well. The connection must not loosen due to slight load and it must be possible to loosen it with manual force. The test was carried out under internal protocol. The luer lock connection test performed could withstand the force until the injection cannula detaches from the plugin connection. The test was carried out under internal protocol. Lastly based on ISO 5356-1 test procedures a separating tensile force is applied on the respiration tube that is connected to the bronchoscope with its female conical connector. No disconnection under a tensile load of 50 Newton for a minimum of 10 seconds was observed.

The DUTAU-NOVATECH® shall be designed atraumatic. The visual inspection of the bronchoscope passed. No sharp edges were found, the product is atraumatic. The test was carried out under internal protocol.

The requirements are fulfilled for all the test samples regarding the rotational torque tests. No damage of the tube and the snap fit connection below the defined load was observed. The test was carried out under internal protocol.

Leakage test which was carried out shows that bronchoscopes have no leakage at clinically relevant pressures. The test was carried out under internal protocol.

9 Shelf Life/Sterilization

Method of Sterilization (reprocessing):	Steam Sterilization
Applied Standards:	ISO 14937:2010 / ISO 17665-1:2006 (equal to ISO 17665:2024, half-cycle approach)
Shelf-Life:	N/A

10 Conclusion

The subject device DUTAU-NOVATECH® is substantially equivalent to predicate device, Karl Storz Bronchoscope Accessories. The DUTAU-NOVATECH® has the same intended use and set of indications for use as the predicate device, both use the same operating principle and incorporates the same basic design as the predicate device. The DUTAU-NOVATECH® has the similar technological characteristics as the predicate device. The tubes of both devices are intended to facilitate the introduction and removal of instruments. They are both made of the same material and their dimensions hardly differ from one another. The tube lengths of the proposed device are within the range of the predicate device. The bronchoscope heads of both devices, consisting of caps and telescope guides, are made of the same materials and offer the same features. Both devices are provided with an injection cannula for jet ventilation and insertion guides (ports) which can be sealed with caps. The subject device and the predicate device both are manually operable.