June 13, 2025

inomed Medizintechnik GmbH
Anja Moerchen
Regulatory Affairs Manager
Im Hausgruen 29
Emmendingen, 79312
Germany

Re: K242852
Trade/Device Name: ALM Tube I.D. 6.0, O.D. 8.2 (520843), ALM Tube I.D. 7.0, O.D. 9.7 (520845), ALM Tube I.D. 7.5, O.D. 10.3 (520846), ALM Tube I.D. 8.0, O.D. 11.0 (520847)
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN, BTR
Dated: May 16, 2025
Received: May 16, 2025

Dear Anja Moerchen:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242852

Device Name

ALM Tube I.D. 6.0, O.D. 8.2 (520843)
ALM Tube I.D. 7.0, O.D. 9.7 (520845)
ALM Tube I.D. 7.5, O.D. 10.3 (520846)
ALM Tube I.D. 8.0, O.D. 11.0 (520847)

Indications for Use *(Describe)*

The ALM Tube is intended for use as a means of providing both an open airway for patient ventilation and for intraoperative neuromonitoring by recording the EMG activity of the laryngeal musculature when connected to an appropriate neuromonitoring device.

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

Date of preparation:	2025-05-16
510(k) Holder:	inomed Medizintechnik GmbH Im Hausgruen 29 79312 Emmendingen, Germany
Submitter and Application Correspondent:	Johannes Hoerth Regulatory Affairs Manager Phone: +49 7641 94 14 836 Email: j.hoerth@inomed.com Ilyas Hamdi Product Manager Phone: +49 7641 94 14 599 Email: i.hamdi@inomed.com
Manufacturing Site:	inomed Medizintechnik GmbH Im Hausgrün 29 79312 Emmendingen, Germany
Trade Name:	ALM Tube
Regulation Medical Specialty:	Ear, Nose & Throat
Classification Regulation:	21 CFR 874.1820 – Surgical nerve stimulator/locator
Product Code:	ETN (Class 2) – Stimulator, Nerve
Subsequent Product Codes:	BTR

Substantially Equivalent Devices:	**Predicate device 510(k) number**	**Predicate device Manufacturer / Model**
	K110989	Neurovision Medical Products, Inc. / Neurovision Ink Printed Endotracheal Tube Electrode LETEIP-1, LETEIP-2

	Reference device 510(k) number	Reference device Manufacturer / Model
	K091874	inomed Medizintechnik GmbH / inomed Adhesive Laryngeal Electrode

Device Description:	The ALM Tube is an endotracheal intubation tube which combines the function of airway ventilation and intraoperative neuromonitoring purposes regarding recording of electrophysiological signals. It combines the recording of EMG signals from the vocal cords to monitor the recurrent laryngeal nerve or the vagal nerve function during surgical procedures. The product is used intraoperatively and is connected to an appropriate neuromonitoring device for signal recording outside of the sterile field via a connection cable. The connection cable is not part of the delivered package.
Intended Use of Subject Device: ALM Tube	The ALM Tube is intended for use as a means of providing both an open airway for patient ventilation and for intraoperative neuromonitoring by recording the EMG activity of the laryngeal musculature when connected to an appropriate neuromonitoring device. This device must be used in connection with the C2 Xplore® or any approved IEC 60601-1, compatible EMG monitoring system with 42802 DIN compatible connectors.
Intended Use of Predicate Device: Neurovision Ink Printed Endotracheal Tube Electrode	The Neurovision Ink Printed Endotracheal Tube Electrode is intended for use during surgery and parasurgical care-only, with any compatible monitoring system, for continuous EMG monitoring and status assessment of the nerves supplying the laryngeal musculature as well as providing an open airway for patient ventilation.
Conclusion of the intended use evaluation:	inomed Medizintechnik GmbH claims that the predicate and subject devices are substantially equivalent in terms of the intended use. Both the predicate and subject devices can be used for providing an open airway for patient ventilation and for the recording of EMG activity of the laryngeal musculature when connected to an appropriate neuromonitoring device.

Technology Comparison:

The technological characteristics of the ALM Tube and the predicate device are equivalent:

	Subject device	**Predicate device**
Device name	ALM Tube	Neurovision Ink Printed Endotracheal Tube Electrode LETEIP-1, NETEIP-2
Manufacturer	inomed Medizintechnik GmbH	Neurovision Medical Products, Inc
Materials	The electrode surface material consists of Conductive Silver Ink, the Tube and Cuff Material is PVC.	The electrode surface material consists of Conductive Silver Ink, the Tube and Cuff Material is PVC.
Reinforcing material	Dielectric coating	Dielectric coating
Tissue contact	The ALM Tube can be divided into direct and indirect contact areas. The direct patient contact area is located in the outer area of the ALM Tube. Indirect patient contact describes the inner surface of the tracheal tube and the tracheal tube connector.	The Neurovision Ink Printed Endotracheal Tube Electrode can be divided into direct and indirect contact areas. The direct patient contact area is located in the outer area of the tube. Indirect patient contact describes the inner surface of the tracheal tube and the tracheal tube connector.
Shelf life	1 year	3 years
Provided sterile	Yes	Yes
Sterilization method	Ethylene Oxide (EO) sterilization	Ethylene Oxide (EO) sterilization
Inner diameter [mm]	• 6.0 • 7.0 • 7.5 • 8.0	• 6.0* • 7.0* • 8.0*
Outer diameter [mm]	• 8.2 • 9.7 • 10.3 • 11.0	• 8.0* • 9.3* • 10.8*
Number of electrodes	8 electrodes	2 or 4 electrodes
Exposed electrode size (for size I.D. 6.0 mm)	• Single electrode area: Electrodes 1, 3, 6 and 8: ~90 mm^2 Electrode 2, 4, 5 and 7: ~99 mm^2	<u>Predicate device:</u> • Single electrode area: Electrodes 1 and 3: ~617 mm^2 Electrode 2: ~222 mm^2,

	• Sum of electrode area: 4*90 mm^2 + 4*99 mm^2 = 756 mm^2 • Width of single electrode: ~ 2 mm • Length of single electrode: Electrodes 2, 4, 5 and 7 ~ 44mm and electrodes 1, 3, 6 and 8 ~ 40 mm	• Sum of electrode area: 2*617 mm^2 + 222 mm^2 = 1456 mm^2 • Width of single electrode: Electrode 1 and 3 ~ 9 mm, Electrode 2 ~3 mm • Length of single electrode: ~71 mm <u>Reference device (article no.: 5140-530-855):</u> • Width of single electrode: ~ 3 mm • Length = 27 mm • Single electrode area: Electrodes: ~86 mm^2 • Sum of electrode area: 8*115 mm^2 = 688 mm^2
	The ALM Tube and the predicate device both feature electrode coverage over the entire circumference of the tube surface. Like the reference device, the ALM Tube incorporates eight electrodes. In contrast, the predicate device utilizes three electrodes, resulting in significantly larger individual electrode surfaces. The ALM Tube exhibits a slightly larger individual electrode area and a greater cumulative active electrode surface compared to the reference device. These differences are not expected to adversely affect device performance.	
Electrode impedance values	0.27 kΩ (average value of impedance measured within neuromonitoring comparative testing)	0.30 kΩ (average value of impedance measured within neuromonitoring comparative testing)
	As the results of the comparative impedance measurement with neuromonitoring system demonstrate, the electrode average value is approximately the same for both products. A difference in electrochemical impedance by spectroscopy was observed between the Cobra® and the ALM tube. However, comparison between the subject device and the reference device shows comparable results, taking into account the variations in material and geometry given.	
Electrical insulation	Electrical insulation on all surfaces until the head of the electrode	Electrical insulation on all surfaces until the head of the electrode
Site of application	Oral (Trachea)	Oral (Trachea)

Single use or reusable	Single use	Single use
Duration of use	≤ 12 hours intubation	Beyond 8 hours is not recommended*

***** The predicate device "*Neurovision Ink Printed Endotracheal Tube Electrode LETEIP-1, NETEIP-2*" is marketed today under the name "*Cobra® EMG Endotracheal Tube*". As the product "*Neurovision Ink Printed Endotracheal Tube Electrode LETEIP-1, NETEIP-2*" is no longer in commercial distribution on the market and due to the lack of data available, this information comes from the currently marketed device "*Cobra® EMG endotracheal tube"*.

Summary of Performance Testing:	
Biocompatibility:	The ALM Tube was tested according to the following standards: - ISO 10993-1:2018 - ISO 10993-2:2022 - ISO 10993-5:2009 - ISO 10993-7:2008 + Amd 1: 2019 - ISO 10993-10:2021 - ISO 10993-11:2017 - ISO 10993-12:2021 - ISO 10993-17:2023 - ISO 10993-18:2020 - ISO 10993-23:2021 - ISO 18562-1:2024 Test results indicate that the ALM Tube complies with the applicable standards.
Sterilization	The ALM Tube was tested according to the following standard: - ISO 11135:2014 + Amd 1: 2018 Test results indicate that the ALM Tube complies with the applicable standards.
Packaging and shelf-life validation	The ALM Tube was tested according to the following standards: - ISO 11607-1:2019+ Amd 1:2023 - ISO 11607-2:2019+ Amd 1:2023 Test results indicate that the ALM Tube complies with the applicable standards.
Software:	The ALM Tube does not contain any kind of software, and therefore, this section does not apply to it.
Electrical Safety:	The ALM Tube is a device which is not electrically powered, but the device should be used with an electrically powered, IEC 60601-1 and IEC 60601-1-2 compliant neuromonitoring system.
Electromagnetic Compatibility:	The ALM Tube is a device which is not electrically powered, but the device should be used with an electrically powered, IEC 60601-1 and IEC 60601-1-2 compliant neuromonitoring system.
Performance Testing – Bench	The ALM Tube was tested for performance in accordance with internal requirements and the following standards: - ISO 5356-1:2015 - ISO 5361:2023 Test results indicate that the ALM Tube complies with the applicable standards, except for clause 6.7.1 of IEC 5361:2023.

Performance Testing – Clinical	No additional clinical testing was performed for the ALM tube. Therefore, this section does not apply.
Human factors / Usability	A user interface evaluation was conducted as knowledge test with representative US citizens.
Conclusion	Verification and validation activities and human factors engineering testing were undertaken in order to establish the performance and safety characteristics of the ALM Tube. The results of these activities demonstrate that the ALM Tube is as safe, effective and perform as well as the predicate device, despite the differences in technology between the subject and predicate device. Therefore, the ALM Tube is considered substantially equivalent to the predicate device.