

K242852 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)Jun 13, 2025
266 days to decisionK242852 · Product code: ETN · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k242852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Sep 20, 2024
Decision date	Jun 13, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Inomed Medizintechnik GmbH
Location	Emmendingen, DE
Contact	Anja Moerchen
Website	https://www.inomed.com/
510(k) history	10 submissions · 10 cleared · 1991-2025

Inomed Medizintechnik GmbH is a medical device manufacturer specializing in intraoperative neuromonitoring and surgical navigation systems. The company operates with a manufacturing facility in Emmendingen, Germany. Inomed has maintained a strong FDA 510(k) regulatory record since 1991. The company has received FDA 510(k) clearances from total submissions, with the most recent clearance in 2025. This demonstrates continued active development and market engagement in specialized surgical technologies. The company's cleared device portfolio spans neurology and otolaryngolog...
