

**K223254 C2 Xplore**Jan 27, 2023  
98 days to decisionK223254 · Product code: **ETN** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k223254/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Oct 21, 2022
Decision date	Jan 27, 2023
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inomed Medizintechnik GmbH</b>
Location	Emmendingen, DE
Contact	Maximilian Wimmer
Website	<a href="https://www.inomed.com/">https://www.inomed.com/</a>
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...

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