

K152505 C2 NerveMonitor SystemFeb 1, 2016
152 days to decisionK152505 · Product code: **ETN** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k152505/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Sep 2, 2015
Decision date	Feb 1, 2016
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Inomed Medizintechnik GmbH
Location	Emmendingen, DE
Contact	SASCHKA BUSCH
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...
