

K042208 ISIS MER SYSTEM/ELEKTA MER SYSTEMMar 18, 2005
214 days to decisionK042208 · Product code: **GZL** · Neurology
Source: <https://www.510kdatabase.net/k042208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Depth (GZL)
Date received	Aug 16, 2004
Decision date	Mar 18, 2005
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Inomed Medizintechnik GmbH
Location	Emmendingen, DE
Contact	ANDERS SKOGLUND
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...
