

**K212166 ISIS Headboxes, ISIS Neurostimulator, ISIS Xpert Plus, ISIS Xpert, ISIS Xpress**Jan 7, 2022  
179 days to decisionK212166 · Product code: **GWF** · Neurology  
Source: <https://www.510kdatabase.net/k212166/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Jul 12, 2021
Decision date	Jan 7, 2022
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inomed Medizintechnik GmbH</b>
Location	Emmendingen, DE
Contact	Tomasz Moszkowski
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...