**CLEARED**

# K233292 ISIS Headboxes, ISIS Neurostimulator, ISIS Xpert Plus, ISIS Xpert, ISIS Xpress

Oct 27, 2023
28 days to decision

K233292 · Product code: **GWF** · Neurology
Source: https://www.510kdatabase.net/k233292/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Stimulator, Electrical, Evoked Response (GWF) |
| Date received | Sep 29, 2023 |
| Decision date | Oct 27, 2023 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Inomed Medizintechnik GmbH** |
| Location | Emmendingen, DE |
| Contact | Tomasz Moszkowski |
| 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...