

K111647 C2 NERVEMONITOR SYSTEM WITH ACCESSORIESOct 6, 2011
115 days to decisionK111647 · Product code: **GWF** · Neurology
Source: <https://www.510kdatabase.net/k111647/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Electrical, Evoked Response (GWF) |
| Date received | Jun 13, 2011 |
| Decision date | Oct 6, 2011 |
| Days to decision | 115 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...
