FDA 510(k) Premarket Notification

# K103246 IPLAN RT

**CLEARED**

Mar 16, 2011
133 days to decision

K103246 · Product code: **MUJ** · Radiology
Source: https://www.510kdatabase.net/k103246/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Planning, Radiation Therapy Treatment (MUJ) |
| Date received | Nov 3, 2010 |
| Decision date | Mar 16, 2011 |
| Days to decision | 133 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Brainlab AG** |
| Location | Heimstetten, DE |
| Contact | ALEXANDER SCHWIERSCH |
| Website | http://brainlab.com |
| 510(k) history | 135 submissions · 135 cleared · 1996-2025 |

Brainlab AG is a digital medical technology company specializing in image-guided surgery and neurology devices. The company operates with a manufacturing facility in Heimstetten, Germany, and develops innovative surgical navigation and alignment systems for cranial, spine, and neurosurgical procedures. Brainlab has received FDA 510(k) clearances from total submissions since its first clearance in 1996. The company maintains a strong regulatory presence in neurology devices, with recent clearances spanning surgical navigation systems, robotic alignment platforms, trajector...

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Device record: https://www.510kdatabase.net/k103246/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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