

K163013 Quantib Brain 1.2Jan 6, 2017
70 days to decisionK163013 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k163013/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Oct 28, 2016 |
| Decision date | Jan 6, 2017 |
| Days to decision | 70 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Quantib B.V. |
| Location | Rotterdam, NL |
| Contact | Rudolf Scholte |
| 510(k) history | 11 submissions · 11 cleared · 2016-2026 |

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