

**K153351 Quantib Brain 1**Jun 17, 2016  
210 days to decisionK153351 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k153351/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 20, 2015
Decision date	Jun 17, 2016
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Quantib B.V.</b>
Location	Rotterdam, NL
Contact	FLOOR VAN LEEUWEN
510(k) history	11 submissions · 11 cleared · 2016-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153351/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026