

**K213737 Quantib ND**Jan 14, 2022  
46 days to decisionK213737 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k213737/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Special                                      |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Nov 29, 2021                                 |
| Decision date         | Jan 14, 2022                                 |
| Days to decision      | 46 days                                      |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Quantib B.V.</b>                     |
| Location       | Rotterdam, NL                           |
| Contact        | Floor van Leeuwen                       |
| 510(k) history | 11 submissions · 11 cleared · 2016-2026 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213737/> 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