

K221106 Quantib ProstateMay 13, 2022
28 days to decisionK221106 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k221106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 15, 2022
Decision date	May 13, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221106/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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