

K253682 DeepHealth ProstateAI

Apr 29, 2026
159 days to decision

K253682 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k253682/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Nov 21, 2025
Decision date	Apr 29, 2026
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	DeepHealth, Inc.
Contact	Kim Ky

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)
