

K242683 QP-Prostate® CADMar 18, 2025
193 days to decisionK242683 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k242683/>**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	Sep 6, 2024
Decision date	Mar 18, 2025
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quibim S.L.
Location	Valencia, ES
Contact	Angel Alberich Bayarri
510(k) history	3 submissions · 3 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John J. Smith

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

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