

K212783 ProstatIDJul 8, 2022
310 days to decisionK212783 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k212783/>**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 1, 2021
Decision date	Jul 8, 2022
Days to decision	310 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Scanmed, LLC
Location	Omaha, NE, US
Contact	Randall Jones
510(k) history	1 submissions · 1 cleared · 2022-2022

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