

K241831 Transpara (2.1.0)Nov 25, 2024
153 days to decisionK241831 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k241831/>**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	Jun 25, 2024
Decision date	Nov 25, 2024
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Screenpoint Medical B.V.
Location	Nijmegen, NL
Contact	Robin Barwegen
510(k) history	7 submissions · 7 cleared · 2018-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241831/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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