

K210404 Transpara 1.7.0Jun 2, 2021
112 days to decisionK210404 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k210404/>**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	Feb 10, 2021
Decision date	Jun 2, 2021
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210404/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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