

K193229 TransparaMar 5, 2020
104 days to decisionK193229 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k193229/>**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 22, 2019
Decision date	Mar 5, 2020
Days to decision	104 days
Third-party review	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

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