

K181704 TransparaNov 21, 2018
147 days to decisionK181704 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k181704/>**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 27, 2018
Decision date	Nov 21, 2018
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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