

K192854 MammoScreenMar 25, 2020
173 days to decisionK192854 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k192854/>**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	Oct 4, 2019
Decision date	Mar 25, 2020
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Therapixel
Location	Valbonne, FR
Contact	Quentin de Snoeck
510(k) history	6 submissions · 6 cleared · 2020-2025

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