

K240301 MammoScreen® (3)

Aug 1, 2024
182 days to decision

K240301 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k240301/>

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 1, 2024
Decision date	Aug 1, 2024
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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