

**K243679 MammoScreen® (4)**Jul 3, 2025  
216 days to decisionK243679 · Product code: **QDQ** · Radiology  
Source: <https://www.510kdatabase.net/k243679/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Nov 29, 2024
Decision date	Jul 3, 2025
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Therapixel</b>
Location	Valbonne, FR
Contact	Pierre Fillard
510(k) history	6 submissions · 6 cleared · 2020-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>MCRA an IQVIA Business</b>
Contact	Alex Cadotte

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243679/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026