

K243685 MammoScreen BDAug 22, 2025
266 days to decisionK243685 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243685/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 29, 2024
Decision date	Aug 22, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243685/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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