FDA 510(k) Premarket Notification

K243685 MammoScreen BD

CLEARED

Aug 22, 2025
266 days to decision

K243685 · 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