FDA 510(k) Premarket Notification

K241561 MammoScreen BD

CLEARED

Oct 2, 2024
124 days to decision

K241561 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k241561/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	May 31, 2024
Decision date	Oct 2, 2024
Days to decision	124 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