

**K241561 MammoScreen BD**Oct 2, 2024  
124 days to decisionK241561 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k241561/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241561/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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