

K240417 ProFound Detection (V4.0)

Nov 8, 2024
269 days to decision

K240417 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k240417/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Feb 13, 2024
Decision date	Nov 8, 2024
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Icad, Inc.
Location	Beavercreek, OH, US
Contact	Spence Hartwell
510(k) history	14 submissions · 14 cleared · 2004-2024

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Device record: <https://www.510kdatabase.net/k240417/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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