

K191994 ProFound AI Software V2.1Oct 4, 2019
70 days to decisionK191994 · Product code: **QDQ** · Radiology
Source: <https://www.510kdatabase.net/k191994/>**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	Jul 26, 2019
Decision date	Oct 4, 2019
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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