FDA 510(k) Premarket Notification

K203822 ProFound AI Software V3.0

CLEARED

Mar 12, 2021
73 days to decision

K203822 · Product code: **QDQ** · Radiology
Source: https://www.510kdatabase.net/k203822/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Dec 29, 2020
Decision date	Mar 12, 2021
Days to decision	73 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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