FDA 510(k) Premarket Notification

K201555 EchoGo Pro

CLEARED

Dec 18, 2020
191 days to decision

K201555 · Product code: **POK** · Radiology
Source: https://www.510kdatabase.net/k201555/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Jun 10, 2020
Decision date	Dec 18, 2020
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ultromics, Ltd.**
Location	Oxford, GB
Contact	Melissa Clark
510(k) history	2 submissions · 2 cleared · 2019-2020