

K233955 Clarius OB AI

Jun 14, 2024
182 days to decision

K233955 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k233955/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 15, 2023
Decision date	Jun 14, 2024
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Clarius Mobile Health Corp.
Location	Vancouver, CA
Contact	Agatha Szeliga
510(k) history	12 submissions · 12 cleared · 2016-2026
