FDA 510(k) Premarket Notification

K231989 LOGIQ E10s, LOGIQ Fortis

CLEARED

Nov 7, 2023
125 days to decision

K231989 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k231989/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 5, 2023
Decision date	Nov 7, 2023
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems Ultrasound and Primary Care Diagnostic,**
Location	Wauwatosa, WI, US
Contact	Bryan Behn
510(k) history	2 submissions · 2 cleared · 2023-2023