FDA 510(k) Premarket Notification

K214039 LOGIQ P10, LOGIQ P9, LOGIQ P8

CLEARED

Mar 22, 2022
89 days to decision

K214039 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k214039/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 23, 2021
Decision date	Mar 22, 2022
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**GE Medical Systems Ultrasound and Primary Care Diagnostics**
Location	Wauwatosa, WI, US
Contact	Bryan Behn
510(k) history	64 submissions · 64 cleared · 2015-2026