FDA 510(k) Premarket Notification

K160277 LOGIQ F8 Expert, LOGIQ F8, LOGIQ F6

CLEARED

Mar 25, 2016
52 days to decision

K160277 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k160277/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 2, 2016
Decision date	Mar 25, 2016
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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