FDA 510(k) Premarket Notification

# K234106 Venue Fit

**CLEARED**

Jun 10, 2024
167 days to decision

K234106 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k234106/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Dec 26, 2023 |
| Decision date | Jun 10, 2024 |
| Days to decision | 167 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 | Karin Shimoni |
| 510(k) history | 64 submissions · 64 cleared · 2015-2026 |