

K220851 VenueJun 27, 2022
96 days to decisionK220851 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k220851/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Mar 23, 2022 |
| Decision date | Jun 27, 2022 |
| Days to decision | 96 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | GE Medical Systems |
| Location | Milwaukee, WI, US |
| Contact | Lee Bush |
| 510(k) history | 169 submissions · 166 cleared · 1989-2022 |

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