

K210743 ACUSON Redwood Diagnostic Ultrasound SystemApr 1, 2021
20 days to decisionK210743 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k210743/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Mar 12, 2021 |
| Decision date | Apr 1, 2021 |
| Days to decision | 20 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Siemens Medical Solutions USA, Inc. |
| Location | Hoffman Estates, IL, US |
| Contact | Sulgue Choi |
| 510(k) history | 778 submissions · 778 cleared · 1980-2026 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Regulatory Technology Services, LLC |
| Contact | Prithul Bom |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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