

**K253457 ACUSON Juniper Diagnostic Ultrasound System**Nov 13, 2025  
38 days to decisionK253457 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k253457/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional  |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN)  |
| Date received         | Oct 6, 2025  |
| Decision date         | Nov 13, 2025                                       |
| Days to decision      | 38 days  |
| Third-party review    | Yes  |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |
| Other names           | ACUSON Juniper Select Diagnostic Ultrasound System |

**APPLICANT**

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|----------------|--|
| Company        | <b>Siemens Medical Solutions USA, Inc.</b> |
| Location       | Hoffman Estates, IL, US                    |
| Contact        | Rapaka Shilpa                              |
| 510(k) history | 778 submissions · 778 cleared · 1980-2026  |

**REGULATORY CONSULTANT**

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|-----------------|--|
| Consulting firm | <b>Regulatory Technology Services, LLC</b> |
| 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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