

**K221599 HS40 Diagnostic Ultrasound System**Aug 22, 2022  
81 days to decisionK221599 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k221599/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received         | Jun 2, 2022                                       |
| Decision date         | Aug 22, 2022                                      |
| Days to decision      | 81 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Samsung Medison Co., Ltd.</b>                              |
| Location       | Seoul, KR   |
| Contact        | Jee Young Ju  |
| Website        | <a href="http://www.medison.com/">http://www.medison.com/</a> |
| 510(k) history | 72 submissions · 72 cleared · 2011-2026                       |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221599/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026