

K210068 HS50 Diagnostic Ultrasound System, HS60 Diagnostic Ultrasound SystemApr 9, 2021
88 days to decisionK210068 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k210068/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Jan 11, 2021 |
| Decision date | Apr 9, 2021 |
| Days to decision | 88 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Samsung Medison Co., Ltd. |
| Location | Seoul, KR |
| Contact | Scully Kim |
| Website | http://www.medison.com/ |
| 510(k) history | 72 submissions · 72 cleared · 2011-2026 |

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