

K191055 HS40 Diagnostic Ultrasound SystemJun 12, 2019
54 days to decisionK191055 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k191055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 19, 2019
Decision date	Jun 12, 2019
Days to decision	54 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191055/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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