

K181336 HS50 / HS60 Diagnostic Ultrasound SystemDec 4, 2018
197 days to decisionK181336 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k181336/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 21, 2018
Decision date	Dec 4, 2018
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181336/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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