

K163691 HS70A Diagnostic Ultrasound SystemFeb 22, 2017
56 days to decisionK163691 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k163691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 28, 2016
Decision date	Feb 22, 2017
Days to decision	56 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163691/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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