

K133505 SONOACE R7 DIAGNOSTIC ULTRASOUND SYSTEMDec 27, 2013
43 days to decisionK133505 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k133505/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 14, 2013
Decision date	Dec 27, 2013
Days to decision	43 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133505/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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