

K162094 RS80A Diagnostic Ultrasound SystemAug 26, 2016
29 days to decisionK162094 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k162094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 28, 2016
Decision date	Aug 26, 2016
Days to decision	29 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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