

**K210959 RS85 Diagnostic Ultrasound System, RS80 EVO
Diagnostic Ultrasound System**Jun 24, 2021
85 days to decisionK210959 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k210959/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 31, 2021
Decision date	Jun 24, 2021
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	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

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