

K240516 RS85 Diagnostic Ultrasound SystemJun 12, 2024
110 days to decisionK240516 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k240516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 23, 2024
Decision date	Jun 12, 2024
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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