

K182932 RS85 Diagnostic Ultrasound SystemFeb 15, 2019
116 days to decisionK182932 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k182932/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 22, 2018
Decision date	Feb 15, 2019
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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