

K211945 V8 Diagnostic Ultrasound SystemSep 8, 2021
77 days to decisionK211945 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k211945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 23, 2021
Decision date	Sep 8, 2021
Days to decision	77 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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