

**K173204 RS85 Diagnostic Ultrasound System**Feb 5, 2018  
126 days to decisionK173204 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k173204/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 2, 2017
Decision date	Feb 5, 2018
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173204/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026