

**K171070 WS80A Diagnostic Ultrasound System**Aug 9, 2017  
121 days to decisionK171070 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k171070/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 10, 2017
Decision date	Aug 9, 2017
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Samsung Medison Co., Ltd.</b>
Location	Seoul, KR
Contact	Emily Woo
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/k171070/> 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