

**K211824 HERA W9, HERA W10 Diagnostic Ultrasound System**Sep 9, 2021  
87 days to decisionK211824 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k211824/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 14, 2021
Decision date	Sep 9, 2021
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Samsung Medison Co., Ltd.</b>
Location	Seoul, KR
Contact	Scully Kim
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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