

**K192319 HERA W9 Diagnostic Ultrasound System, HERA W10  
Diagnostic Ultrasound System**Dec 10, 2019  
106 days to decisionK192319 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k192319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 26, 2019
Decision date	Dec 10, 2019
Days to decision	106 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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