

**K252018 HERA Z20 Diagnostic Ultrasound System**Jan 5, 2026  
189 days to decisionK252018 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k252018/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 30, 2025
Decision date	Jan 5, 2026
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System

**APPLICANT**

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Company	<b>Samsung Medison Co., Ltd.</b>
Location	Seoul, KR
Contact	So-Yeon Jang
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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