

K182595 HERA W10 Diagnostic Ultrasound SystemDec 18, 2018
89 days to decisionK182595 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k182595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 20, 2018
Decision date	Dec 18, 2018
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182595/> Data sourced from FDA 510(k) public records (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. - Generated May 15, 2026