

K230084 HERA W10 Diagnostic Ultrasound SystemApr 21, 2023
100 days to decisionK230084 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k230084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 11, 2023
Decision date	Apr 21, 2023
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HERA W9 Diagnostic Ultrasound System

APPLICANT

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

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