

K242444 HERA W10 Diagnostic Ultrasound SystemNov 27, 2024
103 days to decisionK242444 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k242444/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 16, 2024
Decision date	Nov 27, 2024
Days to decision	103 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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