

K220043 HERA W10 Diagnostic Ultrasound System, HERA W9 Diagnostic Ultrasound System

Apr 5, 2022
90 days to decision

K220043 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k220043/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 5, 2022
Decision date	Apr 5, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k220043/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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