FDA 510(k) Premarket Notification

K180409 HS40 Diagnostic Ultrasound System

CLEARED

May 11, 2018
86 days to decision

K180409 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k180409/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 14, 2018
Decision date	May 11, 2018
Days to decision	86 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.net
Device record: https://www.510kdatabase.net/k180409/ 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 16, 2026