

K254099 EVO Q30 Diagnostic Ultrasound System

Mar 27, 2026
98 days to decision

K254099 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k254099/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 19, 2025
Decision date	Mar 27, 2026
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EVO Q20 Diagnostic Ultrasound System; EVO Q10 Diagnostic Ultrasound System; EVO XQ30 Diagnostic Ultrasound System; EVO XQ20 Diagnostic Ultrasound System; EVO XQ10 Diagnostic Ultrasound System; EVO QH30 Diagnostic Ultrasound System; EVO QH20 Diagnostic Ultrasound System; EVO QH10 Diagnostic Ultrasound System

APPLICANT

Company	Samsung Medison Co., Ltd.
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510(k) history	72 submissions · 72 cleared · 2011-2026

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Device record: <https://www.510kdatabase.net/k254099/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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