

K261412 V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System

Jul 28, 2026
89 days to decision

K261412 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k261412/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 30, 2026
Decision date	Jul 28, 2026
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System; V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System; V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System; V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System;

APPLICANT

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510(k) history	73 submissions · 73 cleared · 2011-2026