

**K212959 ACUSON AcuNav Volume Intracardiac
Echocardiography(ICE) Catheter**

Oct 15, 2021
29 days to decision

K212959 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k212959/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Sep 16, 2021
Decision date	Oct 15, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	HyunJung Lee
510(k) history	778 submissions · 778 cleared · 1980-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k212959/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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