

K163478 AcuNav Volume ICE CatheterFeb 9, 2017
59 days to decisionK163478 · Product code: **OBJ** · CardiovascularSource: <https://www.510kdatabase.net/k163478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Dec 12, 2016
Decision date	Feb 9, 2017
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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