

**K250955 XC11 ICE System, USA**Oct 22, 2025  
205 days to decisionK250955 · Product code: **OBJ** · CardiovascularSource: <https://www.510kdatabase.net/k250955/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Mar 31, 2025
Decision date	Oct 22, 2025
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Yorlabs, Inc.</b>
Location	Carlsbad, CA, US
Contact	Wanda Carpinella
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250955/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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