

**K252945 Novasight Hybrid System**Apr 17, 2026  
214 days to decisionK252945 · Product code: **OBJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k252945/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Sep 15, 2025
Decision date	Apr 17, 2026
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Conavi Medical, Inc.</b>
Location	Toronto, CA
Contact	David Zhang
510(k) history	3 submissions · 3 cleared · 2017-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Avania</b>
Contact	Sophia Farcas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)

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