FDA 510(k) Premarket Notification

K252945 Novasight Hybrid System

CLEARED

Apr 17, 2026
214 days to decision

K252945 · Product code: **OBJ** · Cardiovascular
Source: https://www.510kdatabase.net/k252945/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Avania**
Contact	Sophia Farcas

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