

K253399 Visions® PV .014P RX Digital IVUS CatheterOct 28, 2025
28 days to decisionK253399 · Product code: **OBJ** · CardiovascularSource: <https://www.510kdatabase.net/k253399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Sep 30, 2025
Decision date	Oct 28, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Visions® PV .018 Digital IVUS Catheter

APPLICANT

Company	Volcano Corporation (Dba Philips Image Guided Therapy Device
Location	San Diego, CA, US
Contact	Aaron Niklaus
510(k) history	1 submissions · 1 cleared · 2025-2025

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