

**K251915 Amethyst HP PTA OTW 0.035 Catheter**Dec 18, 2025  
178 days to decisionK251915 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k251915/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jun 23, 2025
Decision date	Dec 18, 2025
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Natec Medical , Ltd.</b>
Location	Crofton, MD, US
Contact	Pallippatt Roy Devassy
510(k) history	11 submissions · 11 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251915/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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