

**K242756 Introducer Sheath (PFlexi00L065, PFlexi00L070, PFlexi00L075, PFlexi00L080, PFlexi00L090, PFlexi30L065, PFlexi30L070, PFlexi30L075, PFlexi30L080, PFlexi30L090, PFlexi45L065, PFlexi45L070, PFlexi45L075, PFlexi45L080, PFlexi45L090, PFlexi60L065, PFlexi60L070, PFlexi60L075, PFlexi60L080, PFlexi60L090)**

Nov 8, 2024  
57 days to decision

K242756 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k242756/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 12, 2024
Decision date	Nov 8, 2024
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pulnovo Medical (Wuxi) Co., Ltd.</b>
Location	Wuxi, CN
Contact	Wen Gu
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k242756/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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