FDA 510(k) Premarket Notification

CLEARED

Nov 8, 2024
57 days to decision

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

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

SUBMISSION DETAILS

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

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