

K250439 Catapult Guide SheathMar 16, 2025
30 days to decisionK250439 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k250439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Feb 14, 2025
Decision date	Mar 16, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	4F; 15cm (US-34015-F-ST-H); Catapult Guide Sheath; 4F; 45cm (US-34045-F-ST-H); Catapult Guide Sheath; 4F; 60cm (US-34060-F-ST-H); Catapult Guide Sheath; 4F; 90cm (US-34090-F-ST-H); Catapult Guide Sheath; 4F; 130cm (US-34130-F-ST-H); Catapult Guide Sheath; 5F; 15cm (US-35015-F-ST-H); Catapult Guide Sheath; 5F; 45cm (US-35045-F-ST-H); Catapult Guide Sheath; 5F; 45cm; Hockey Stick (US-35045-F-HS-H); Catapult Guide Sheath; 5F; 45cm; Multipurpose (US-35045-F-MP-H); Ca

APPLICANT

Company	Contract Medical International, GmbH
Location	Dresden, DE
Contact	Jan Kubicek
510(k) history	7 submissions · 7 cleared · 2015-2025

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