

K230704 RAIN Sheath™ Tibial Pedal IntroducerApr 24, 2023
41 days to decisionK230704 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k230704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 14, 2023
Decision date	Apr 24, 2023
Days to decision	41 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cordis US Corp
Location	Miami Lakes, FL, US
Contact	Wai Morgan
510(k) history	4 submissions · 4 cleared · 2022-2024

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