

K193160 Glidesheath Slender Tibial Pedal KitDec 3, 2019
18 days to decisionK193160 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k193160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Nov 15, 2019
Decision date	Dec 3, 2019
Days to decision	18 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Medical Coporation
Location	Elkton, MD, US
Contact	Liang Lu
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193160/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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