

K181237 Glidesheath Slender Tibial Pedal KitAug 3, 2018
85 days to decisionK181237 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k181237/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | May 10, 2018 |
| Decision date | Aug 3, 2018 |
| Days to decision | 85 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Terumo Medical Corporation |
| Location | Elkton, MD, US |
| Contact | Liang Lu |
| 510(k) history | 14 submissions · 14 cleared · 2011-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181237/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026