

K182243 The CVC WAND Safety Introducer with Valved Peelable SheathSep 18, 2018
29 days to decisionK182243 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k182243/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Aug 20, 2018 |
| Decision date | Sep 18, 2018 |
| Days to decision | 29 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Access Scientific, LLC |
| Location | San Diego, CA, US |
| Contact | Martina Nguyen |
| 510(k) history | 6 submissions · 6 cleared · 2013-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182243/> 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 June 28, 2026