

K222184 Introducer Sheath KitsFeb 21, 2023
214 days to decisionK222184 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k222184/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Jul 22, 2022 |
| Decision date | Feb 21, 2023 |
| Days to decision | 214 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Beijing Demax Medical Technology Co.,Ltd |
| Location | Guangzhou, CN |
| Contact | Anny Zhang |
| 510(k) history | 4 submissions · 4 cleared · 2015-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222184/> 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