

K201288 ExpanSure Large Access Transseptal DilatorJun 12, 2020
29 days to decisionK201288 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k201288/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Dilator, Vessel, For Percutaneous Catheterization (DRE) |
| Date received | May 14, 2020 |
| Decision date | Jun 12, 2020 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Baylis Medical Company, Inc. |
| Location | Mississauga, Ontario, CA |
| Contact | May Tsai |
| 510(k) history | 24 submissions · 24 cleared · 2012-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201288/> 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 14, 2026