

K233647 VersaCross Connect™ Transseptal DilatorDec 14, 2023
30 days to decisionK233647 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k233647/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Dilator, Vessel, For Percutaneous Catheterization (DRE) |
| Date received | Nov 14, 2023 |
| Decision date | Dec 14, 2023 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

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