

K252478 Vaccess™ CT Low-Profile Power-Injectable Implantable Port

Sep 5, 2025
29 days to decision

K252478 · Product code: LJT · General Hospital
Source: <https://www.510kdatabase.net/k252478/>

SUBMISSION DETAILS

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT) |
| Date received | Aug 7, 2025 |
| Decision date | Sep 5, 2025 |
| Days to decision | 29 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Vaccess™ CT Power-Injectable Implantable Port; PowerPort™ duo M.R.I.™ Implantable Port |

APPLICANT

| | |
|----------------|---|
| Company | Bard Access Systems, Inc. |
| Location | Salt Lake City, UT, US |
| Contact | Kaitlyn Nielsen |
| 510(k) history | 21 submissions · 20 cleared · 1993-2025 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k252478/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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