

K221319 BD Alaris™ Pump Epidural Infusion SetJul 21, 2023
441 days to decisionK221319 · Product code: **PWH** · General Hospital
Source: <https://www.510kdatabase.net/k221319/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Administrations Sets With Neuraxial Connectors (PWH) |
| Date received | May 6, 2022 |
| Decision date | Jul 21, 2023 |
| Days to decision | 441 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Care Fusion |
| Location | Waukegan, IL, US |
| Contact | Paulina Davis |
| 510(k) history | 34 submissions · 29 cleared · 2010-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221319/> 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