

K162219 CADD® Infusion Disposables Portfolio with NRFit™ connectorsJul 20, 2017
346 days to decisionK162219 · Product code: **PWH** · General Hospital
Source: <https://www.510kdatabase.net/k162219/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Administrations Sets With Neuraxial Connectors (PWH) |
| Date received | Aug 8, 2016 |
| Decision date | Jul 20, 2017 |
| Days to decision | 346 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Smiths Medical Asd, Inc. |
| Location | Rockland, MA, US |
| Contact | Wendy J. Kivens |
| 510(k) history | 52 submissions · 52 cleared · 2004-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162219/> 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 June 1, 2026