

K261530 iiSure Infusion SetJun 3, 2026
26 days to decisionK261530 · Product code: **FPA** · Chemistry
Source: <https://www.510kdatabase.net/k261530/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | May 8, 2026 |
| Decision date | Jun 3, 2026 |
| Days to decision | 26 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Deka Research and Development |
| Location | Manchester, NH, US |
| Contact | Paul Smolenski |
| 510(k) history | 12 submissions · 12 cleared · 2015-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k261530/> 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 9, 2026