

K140425 CONTRAST MODULATION SYSTEMJun 11, 2014
112 days to decisionK140425 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k140425/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Injector And Syringe, Angiographic (DXT) |
| Date received | Feb 19, 2014 |
| Decision date | Jun 11, 2014 |
| Days to decision | 112 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Osprey Medical, Inc. |
| Location | Eden Prairie, MN, US |
| Contact | JILL MUNSINGER |
| 510(k) history | 14 submissions · 14 cleared · 2013-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140425/> 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 29, 2026