

K244061 X-Wire GuidewireAug 26, 2025
238 days to decisionK244061 · Product code: **MOF** · Neurology
Source: <https://www.510kdatabase.net/k244061/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Guide, Wire, Catheter, Neurovasculature (MOF) |
| Date received | Dec 31, 2024 |
| Decision date | Aug 26, 2025 |
| Days to decision | 238 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Imperative Care, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | Shivani Patel |
| 510(k) history | 17 submissions · 17 cleared · 2018-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k244061/> 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 13, 2026