

**K141060 CHORD-X PRE-MEASURED LOOPS FOR MITRAL
CHORDAL REPLACEMENT**Jun 6, 2014
43 days to decisionK141060 · Product code: **PAW** · Cardiovascular
Source: <https://www.510kdatabase.net/k141060/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture For Chordae Tendinae Repair Or Replacement (PAW) |
| Date received | Apr 24, 2014 |
| Decision date | Jun 6, 2014 |
| Days to decision | 43 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | On-X Life Technologies, Inc. |
| Location | Austin, TX, US |
| Contact | JOHN ELY |
| 510(k) history | 1 submissions · 1 cleared · 2014-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141060/>, 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 6, 2026