

K122415 X-FIX DYNAMIC EXTERNAL DISTRACTORMar 15, 2013
219 days to decisionK122415 · Product code: HTY · Orthopedic
Source: <https://www.510kdatabase.net/k122415/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pin, Fixation, Smooth (HTY) |
| Date received | Aug 8, 2012 |
| Decision date | Mar 15, 2013 |
| Days to decision | 219 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Arex USA, LLC |
| Location | Edgewater, FL, US |
| Contact | CHARLES HOKANSON |
| 510(k) history | 1 submissions · 1 cleared · 2013-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122415/> 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 18, 2026