

K131566 ARIX HAND SYSTEMNov 4, 2013
158 days to decisionK131566 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k131566/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | May 30, 2013 |
| Decision date | Nov 4, 2013 |
| Days to decision | 158 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Jeil Medical Corporation |
| Location | Deer Field, IL, US |
| Contact | JI-EUN KIM |
| 510(k) history | 53 submissions · 53 cleared · 2002-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131566/> 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 17, 2026