

K212601 DRPx Locking Distal Radius Plate SystemApr 5, 2022
231 days to decisionK212601 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k212601/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Aug 17, 2021 |
| Decision date | Apr 5, 2022 |
| Days to decision | 231 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Orthopaedic Implant Company |
| Location | Reno, NV, US |
| Contact | Douglas Fulton |
| 510(k) history | 10 submissions · 10 cleared · 2014-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212601/> 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 27, 2026