

K153207 Additive Orthopaedics Bone Wedge SystemSep 7, 2016
307 days to decisionK153207 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k153207/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Nov 5, 2015 |
| Decision date | Sep 7, 2016 |
| Days to decision | 307 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Additive Orthopaedics, LLC |
| Location | Little Silver, NJ, US |
| Contact | GREGORY KOWALCZYK |
| 510(k) history | 6 submissions · 6 cleared · 2016-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153207/> 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