

K253046 HERA Interlocking Intramedullary Nailing SystemJun 16, 2026
267 days to decisionK253046 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k253046/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received | Sep 22, 2025 |
| Decision date | Jun 16, 2026 |
| Days to decision | 267 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | ZheJiang Decans Medical Devices Co., Ltd. |
| Location | Jiaxing, CN |
| Contact | Haifeng Liu |
| 510(k) history | 11 submissions · 11 cleared · 2024-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253046/> 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 July 10, 2026