

K163627 Shotel Ankle Arthrodesis Nail SystemSep 14, 2017
266 days to decisionK163627 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k163627/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received | Dec 22, 2016 |
| Decision date | Sep 14, 2017 |
| Days to decision | 266 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biopro, Inc. |
| Location | Port Huron, MI, US |
| Contact | Dave Mrak |
| 510(k) history | 41 submissions · 35 cleared · 1987-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163627/> 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 16, 2026