

K191632 PROFEMUR TL2 StemsOct 7, 2019
110 days to decisionK191632 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k191632/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO) |
| Date received | Jun 19, 2019 |
| Decision date | Oct 7, 2019 |
| Days to decision | 110 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Microport Orthopedics, Inc. |
| Location | Arlington, TN, US |
| Contact | Sneh Pingle |
| 510(k) history | 37 submissions · 37 cleared · 2014-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191632/> 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