

K912641 BIOPRO ZIRALLOY MODULAR FEMORAL HEADSNov 27, 1991
166 days to decisionK912641 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k912641/>**SUBMISSION DETAILS**

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|-----------------------|--|
| 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 14, 1991 |
| Decision date | Nov 27, 1991 |
| Days to decision | 166 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912641/> 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