

**K991622 26 MM CAST COCR HEAD AND POLYETHYLENE
ACETABULAR SHELL LINER**Jul 14, 1999
64 days to decisionK991622 · Product code: JDI · Orthopedic
Source: <https://www.510kdatabase.net/k991622/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI) |
| Date received | May 11, 1999 |
| Decision date | Jul 14, 1999 |
| Days to decision | 64 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Stelkast Company |
| Location | Pittsburgh, PA, US |
| Contact | DONALD A STEVENS |
| 510(k) history | 40 submissions · 37 cleared · 1994-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991622/> 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 18, 2026