

K971426 HEADLOC CERAMIC HEADJul 9, 1997
83 days to decisionK971426 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k971426/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Apr 17, 1997
Decision date	Jul 9, 1997
Days to decision	83 days
Third-party review	No

APPLICANT

Company	Ortho Development Corp.
Location	Draper, UT, US
Contact	CAROL J FREASIER
510(k) history	45 submissions · 43 cleared · 1996-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971426/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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