

K964395 PATIENT SPECIFIC IMPLANT (PSI) HIP FEMORAL COMPONENTJan 27, 1997
84 days to decisionK964395 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k964395/>**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	Nov 4, 1996
Decision date	Jan 27, 1997
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hayes Medical, Inc.
Location	Sacramento, CA, US
Contact	BRIAN T CLEARY
510(k) history	12 submissions · 11 cleared · 1995-2007

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