

K003316 OTI CERAMIC FEMORAL HEAD SYSTEMJan 19, 2001
88 days to decisionK003316 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k003316/>**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	Oct 23, 2000
Decision date	Jan 19, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Osteoimplant Technology, Inc.
Location	Hunt Valley, MD, US
Contact	SAM SON
510(k) history	21 submissions · 20 cleared · 1996-2005

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