

K964924 OMEGA TOTAL HIP SYSTEM FOR USE WITHOUT BONE CEMENT (LINE EXTENSION)Mar 7, 1997
88 days to decisionK964924 · Product code: LPH · Orthopedic
Source: <https://www.510kdatabase.net/k964924/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Dec 9, 1996
Decision date	Mar 7, 1997
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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964924/>; 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 20, 2026