

**K980774 OSTEONICS GAP-II RESTORATION ACETABULAR SHELLS**Apr 29, 1998  
58 days to decisionK980774 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k980774/>**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	Mar 2, 1998
Decision date	Apr 29, 1998
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Osteonics Corp.</b>
Location	Mchenry, IL, US
Contact	KATE SUTTON
510(k) history	178 submissions · 136 cleared · 1980-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980774/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 21, 2026