

**K012462 THEKEN LARGE CEMENT RESTRICTOR**Oct 29, 2001  
89 days to decisionK012462 · Product code: **JDK** · Orthopedic  
Source: <https://www.510kdatabase.net/k012462/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Prosthesis, Hip, Cement Restrictor (JDK)
Date received	Aug 1, 2001
Decision date	Oct 29, 2001
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Theken Surgical,Llc</b>
Location	Barberton, OH, US
Contact	RANDY THEKEN
510(k) history	6 submissions · 4 cleared · 1998-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012462/> 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 20, 2026