

K012278 THEKEN SMALL CEMENT RESTRICTOROct 17, 2001
90 days to decisionK012278 · Product code: **JDK** · Orthopedic
Source: <https://www.510kdatabase.net/k012278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Prosthesis, Hip, Cement Restrictor (JDK)
Date received	Jul 19, 2001
Decision date	Oct 17, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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