FDA 510(k) Premarket Notification

K012462 THEKEN LARGE CEMENT RESTRICTOR

CLEARED

Oct 29, 2001
89 days to decision

K012462 · Product code: **JDK** · Orthopedic
Source: https://www.510kdatabase.net/k012462/

SUBMISSION DETAILS

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

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