K102323 CERVICAL STANDALONE INTERVERTEBRAL BODY FUSION DEVICE

CLEARED

Dec 16, 2010
121 days to decision

K102323 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k102323/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Aug 17, 2010
Decision date	Dec 16, 2010
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Theken Spine, LLC**
Location	Akron, OH, US
Contact	DALE DAVISON
510(k) history	23 submissions · 23 cleared · 2007-2012

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k102323/ 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 18, 2026