

K083863 THEKEN ATOLL OCT SPINAL SYSTEMMar 27, 2009
88 days to decisionK083863 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k083863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Dec 29, 2008
Decision date	Mar 27, 2009
Days to decision	88 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

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