

K983622 BODYFORM THORACO-LUMBAR FIXATION SYSTEMDec 30, 1998
76 days to decisionK983622 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k983622/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Oct 15, 1998
Decision date	Dec 30, 1998
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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