

K111843 ACUFEX DIRECTOR APPLICATION ANATOMIC GUIDE SYSTEMNov 14, 2011
138 days to decisionK111843 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k111843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 29, 2011
Decision date	Nov 14, 2011
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew Inc., Endoscopy Div.
Location	Andover, MA, US
Contact	JANICE HASELTON
510(k) history	10 submissions · 10 cleared · 2007-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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