

K041389 SYNTHES CONTOURED SYNEMESH SPACEROct 1, 2004
129 days to decisionK041389 · Product code: **MQP** · Orthopedic
Source: <https://www.510kdatabase.net/k041389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	May 25, 2004
Decision date	Oct 1, 2004
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes Spine
Location	Paoli, PA, US
Contact	ANGELA MIKROULIS
510(k) history	36 submissions · 32 cleared · 1995-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041389/> 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 20, 2026