

K091994 MOUNTAINEER LAMINOPLASTY SYSTEMJan 7, 2010
189 days to decisionK091994 · Product code: **NQW** · Orthopedic
Source: <https://www.510kdatabase.net/k091994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spine, Plate, Laminoplasty, Metal (NQW)
Date received	Jul 2, 2009
Decision date	Jan 7, 2010
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Depuy Spine, Inc.
Location	Raynham, MA, US
Contact	DAPHNEY GERMAIN
510(k) history	68 submissions · 67 cleared · 2004-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091994/> 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 June 19, 2026