

K090315 STAXX XD SYSTEMSep 3, 2009
206 days to decisionK090315 · Product code: **MQP** · Orthopedic
Source: <https://www.510kdatabase.net/k090315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Feb 9, 2009
Decision date	Sep 3, 2009
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spine Wave, Inc.
Location	Shelton, CT, US
Contact	ROAIDA RIZKALLAH
510(k) history	57 submissions · 57 cleared · 2004-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090315/> 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 19, 2026