

K102315 STAXX XDL SYSTEMAug 19, 2011
368 days to decisionK102315 · Product code: **MQP** · Orthopedic
Source: <https://www.510kdatabase.net/k102315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Aug 16, 2010
Decision date	Aug 19, 2011
Days to decision	368 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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