

K243816 Testa TP Pivoting Spacer SystemJun 27, 2025
197 days to decisionK243816 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k243816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 12, 2024
Decision date	Jun 27, 2025
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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