

K241438 Signus Tetris™ StSep 11, 2024
113 days to decisionK241438 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k241438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 21, 2024
Decision date	Sep 11, 2024
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Signus Tetris™ R St

APPLICANT

Company	Signus Medizintechnik GmbH
Location	Minneapolis, MN, US
Contact	Antje Schmidt
510(k) history	23 submissions · 22 cleared · 1999-2025

REGULATORY CONSULTANT

Consulting firm	Jalex Medical, LLC
Contact	Chhavy Tep-Cullison

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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