FDA 510(k) Premarket Notification

K243188 CYLOX® ST

CLEARED

Feb 11, 2025
134 days to decision

K243188 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k243188/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 30, 2024
Decision date	Feb 11, 2025
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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	Emily Szabo

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