

**K162531 STERISPINE CC**Dec 29, 2016  
111 days to decisionK162531 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k162531/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 9, 2016
Decision date	Dec 29, 2016
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Safe Orthopaedics</b>
Location	Eragny Sur Oise, FR
Contact	SOPHIE REHAULT
510(k) history	13 submissions · 13 cleared · 2011-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162531/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 18, 2026