

**K243659 FLASH™ Facet Fusion Instruments, IsoTis® Facet Fusion Instruments**Apr 2, 2025  
126 days to decisionK243659 · Product code: **OLO** · Orthopedic  
Source: <https://www.510kdatabase.net/k243659/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Nov 27, 2024
Decision date	Apr 2, 2025
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SeaSpine Orthopedics Corporation</b>
Location	Carlsbad, CA, US
Contact	Cindy Toyama
510(k) history	66 submissions · 66 cleared · 2016-2025

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