

**K213791 Unispace SA Cervical Cage**Aug 5, 2022  
242 days to decisionK213791 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k213791/>**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	Dec 6, 2021
Decision date	Aug 5, 2022
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edisoninno Co., Ltd.</b>
Location	Uijeongbu-Si, KR
Contact	So-yeon Jang
510(k) history	1 submissions · 1 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213791/> 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 May 27, 2026