

K234119 UniSpace® Stand-Alone C CageApr 19, 2024
113 days to decisionK234119 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k234119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Dec 28, 2023
Decision date	Apr 19, 2024
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innosys Co., Ltd.
Location	Uijeongbu-Si, KR
Contact	Chae-Hyeon Kim
510(k) history	4 submissions · 4 cleared · 2023-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k234119/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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