

K210573 Velofix SA Cervical CageNov 19, 2021
266 days to decisionK210573 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k210573/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Feb 26, 2021
Decision date	Nov 19, 2021
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	U&I Corporation
Location	Uijeongbu-Si, Gyeonggi-Do, KR
Contact	Jee-Ae Bang
510(k) history	23 submissions · 23 cleared · 2013-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210573/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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