

K253041 3d Cage Cervical

Jul 23, 2026
304 days to decision

K253041 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k253041/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Sep 22, 2025
Decision date	Jul 23, 2026
Days to decision	304 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fims Co., Ltd.
Location	Suwon-Si, KR
Contact	Lee Jiyeon
510(k) history	2 submissions · 2 cleared · 2019-2026