

K222041 CYGNUS-C Standalone ACIF SystemFeb 9, 2023
213 days to decisionK222041 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k222041/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jul 11, 2022
Decision date	Feb 9, 2023
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GS Medical Co., Ltd.
Location	Seoul, KR
Contact	Sam Camp
510(k) history	18 submissions · 18 cleared · 2006-2024

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