

K240715 Idys® C ZP 3DTiMar 22, 2024
7 days to decisionK240715 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k240715/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Mar 15, 2024
Decision date	Mar 22, 2024
Days to decision	7 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Clariance
Location	Cumming, GA, US
Contact	Magalie Hennequin
510(k) history	10 submissions · 10 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240715/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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