

K260036 NeckTune™ 3D SA Cervical CageJun 15, 2026
160 days to decisionK260036 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k260036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jan 6, 2026
Decision date	Jun 15, 2026
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medyssey Co, Ltd.
Location	Santa Fe Springs, CA, US
Contact	Hyokyeong Lee
510(k) history	12 submissions · 12 cleared · 2009-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260036/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 11, 2026