FDA 510(k) Premarket Notification

K242260 aprevo® Cervical ACDF

CLEARED

Nov 15, 2024
107 days to decision

K242260 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k242260/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jul 31, 2024
Decision date	Nov 15, 2024
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	aprevo® Cervical ACDF-X; aprevo® Cervical ACDF-X NO CAM

APPLICANT

Company	**Carlsmed, Inc.**
Location	La Jolla, CA, US
Contact	Karen Liu
510(k) history	20 submissions · 20 cleared · 2020-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k242260/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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