FDA 510(k) Premarket Notification

K233594 Genesys Spine 3DP AIS-C II Cervical Interbody System

CLEARED

Dec 13, 2023
35 days to decision

K233594 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k233594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Nov 8, 2023
Decision date	Dec 13, 2023
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Genesys Spine**
Location	Austin, TX, US
Contact	Andrew Davison
510(k) history	31 submissions · 31 cleared · 2010-2025