FDA 510(k) Premarket Notification

K181295 Genesys Spine AIS-C Cervical Stand-Alone System

CLEARED

Aug 29, 2018
105 days to decision

K181295 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k181295/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	May 16, 2018
Decision date	Aug 29, 2018
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Genesys Spine**
Location	Austin, TX, US
Contact	Benjamin V. Keller
510(k) history	31 submissions · 31 cleared · 2010-2025