FDA 510(k) Premarket Notification

K220096 Genesys Spine 3DP Lumbar Interbody System

CLEARED

Mar 9, 2022
56 days to decision

K220096 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k220096/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 12, 2022
Decision date	Mar 9, 2022
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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