FDA 510(k) Premarket Notification

CLEARED

K161404 Genesys Spine Apache® Lateral Lumbar Interbody Fusion System

Jul 21, 2016
62 days to decision

K161404 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k161404/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 20, 2016
Decision date	Jul 21, 2016
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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