FDA 510(k) Premarket Notification

K183560 Luna 3D GEN2 Interbody Fusion System

CLEARED

May 23, 2019
154 days to decision

K183560 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k183560/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 20, 2018
Decision date	May 23, 2019
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Benvenue Medical, Inc.**
Location	Mountain View, CA, US
Contact	Laurent Schaller
510(k) history	8 submissions · 8 cleared · 2007-2020

REGULATORY CONSULTANT

Consulting firm	**Musculoskeletal Clinical Regulatory Advisers, LLC**
Contact	Justin Eggleton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov