FDA 510(k) Premarket Notification

K162431 Luna 3D Interbody Fusion System

CLEARED

Nov 17, 2016
78 days to decision

K162431 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k162431/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 31, 2016
Decision date	Nov 17, 2016
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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