FDA 510(k) Premarket Notification

K181702 Tranquil-L Interbody System

CLEARED

Sep 21, 2018
86 days to decision

K181702 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181702/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 27, 2018
Decision date	Sep 21, 2018
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nexus Spine, LLC**
Location	Salt Lake City, UT, US
Contact	Jared Crocker
Website	https://nexusspine.com
510(k) history	17 submissions · 17 cleared · 2014-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k181702/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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