FDA 510(k) Premarket Notification

CLEARED

K180822 VariLift-LX Interbody Fusion System, VariLift-C Interbody Fusion System

Jan 28, 2019
304 days to decision

K180822 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k180822/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 30, 2018
Decision date	Jan 28, 2019
Days to decision	304 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Wenzel Spine, Inc.**
Location	Austin, TX, US
Contact	Beckinam Nowatzke
510(k) history	6 submissions · 6 cleared · 2013-2025