FDA 510(k) Premarket Notification

K171151 ACRON™ TLIF System

CLEARED

Apr 27, 2018
372 days to decision

K171151 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k171151/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 20, 2017
Decision date	Apr 27, 2018
Days to decision	372 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinemed Ges.M.B.H**
Location	Wien, AT
Contact	Andreas Bernegger
510(k) history	1 submissions · 1 cleared · 2018-2018