FDA 510(k) Premarket Notification

K172083 Idys™ ALIF System

CLEARED

Nov 8, 2017
121 days to decision

K172083 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k172083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jul 10, 2017
Decision date	Nov 8, 2017
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Clariance, Sas**
Location	Beaurains, FR
Contact	Pascal Rokegem
510(k) history	11 submissions · 11 cleared · 2016-2021