FDA 510(k) Premarket Notification

K202032 Idys LLIF 3DTi

CLEARED

Apr 1, 2021
253 days to decision

K202032 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k202032/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jul 22, 2020
Decision date	Apr 1, 2021
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice M. Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov