FDA 510(k) Premarket Notification

K200919 Idys ALIF 3DTi

CLEARED

Apr 12, 2021
371 days to decision

K200919 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k200919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 6, 2020
Decision date	Apr 12, 2021
Days to decision	371 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Clariance**
Location	Cumming, GA, US
Contact	Fadwa Bahr
510(k) history	10 submissions · 10 cleared · 2012-2025

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