FDA 510(k) Premarket Notification

K243670 Idys® LIF

CLEARED

Dec 31, 2024
34 days to decision

K243670 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k243670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 27, 2024
Decision date	Dec 31, 2024
Days to decision	34 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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