FDA 510(k) Premarket Notification

CLEARED

K242509 HAnano InterFuse(R) Modular Interbody

Sep 19, 2024
28 days to decision

K242509 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k242509/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 22, 2024
Decision date	Sep 19, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Next Orthosurgical**
Location	Round Rock, TX, US
Contact	Misty Calkins
510(k) history	6 submissions · 6 cleared · 2013-2024

REGULATORY CONSULTANT

Consulting firm	**Jalex Medical**
Contact	Chhavy Tep-Cullison

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