FDA 510(k) Premarket Notification

CLEARED

K234087 restor3d TIDAL Lumbar Interbody Fusion System

Jan 22, 2024
31 days to decision

K234087 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k234087/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 22, 2023
Decision date	Jan 22, 2024
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Restor3d**
Location	Durham, NC, US
Contact	Anika Moorjani
510(k) history	11 submissions · 11 cleared · 2020-2025