FDA 510(k) Premarket Notification

K240250 3D Printed PEEK Interbody System

CLEARED

Sep 17, 2024
231 days to decision

K240250 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k240250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 30, 2024
Decision date	Sep 17, 2024
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nvision Biomedical Technologies, Inc.**
Location	San Antonio, TX, US
Contact	Diana Langham
510(k) history	24 submissions · 24 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	**Watershed Idea Foundry, Inc. (Dba Spitrex 3D)**
Contact	Jeffrey Brittan

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