FDA 510(k) Premarket Notification

CLEARED

K222015 Integral Titanium Cervical Interbody

Jul 5, 2023
362 days to decision

K222015 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k222015/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jul 8, 2022
Decision date	Jul 5, 2023
Days to decision	362 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	**Nvision Biomedical Technologies**
Contact	Analaura Villarreal-Berain

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