FDA 510(k) Premarket Notification

K222107 Black Diamond™ POCT Spinal System

CLEARED

Nov 3, 2022
108 days to decision

K222107 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k222107/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Jul 18, 2022
Decision date	Nov 3, 2022
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osseus Fusion Systems**
Location	Dallas, TX, US
Contact	Jonathan Rosen
510(k) history	5 submissions · 5 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	**Jalex Medical, LLC**
Contact	Daniel Johnson

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