FDA 510(k) Premarket Notification

K223043 The Integrity Spine Core System

CLEARED

Mar 20, 2023
179 days to decision

K223043 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k223043/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Sep 22, 2022
Decision date	Mar 20, 2023
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Integrity Spine**
Location	Austin, TX, US
Contact	Timothy Leak
510(k) history	2 submissions · 2 cleared · 2013-2023

REGULATORY CONSULTANT

Consulting firm	**Jalex Medical, LLC**
Contact	Jennifer Palinchik

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