FDA 510(k) Premarket Notification

K241258 Ingenix Spinal System

CLEARED

Jun 4, 2024
29 days to decision

K241258 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k241258/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 6, 2024
Decision date	Jun 4, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ingenium Spine**
Location	Phoenix, AZ, US
Contact	David Brumfield
510(k) history	2 submissions · 2 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Christine Scifert

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

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Device record: https://www.510kdatabase.net/k241258/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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