FDA 510(k) Premarket Notification

K241863 Erisma® Lp Spinal Fixation System

CLEARED

Jul 24, 2024
27 days to decision

K241863 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k241863/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 27, 2024
Decision date	Jul 24, 2024
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Erisma® LP MIS

APPLICANT

Company	**Clariance**
Location	Cumming, GA, US
Contact	Magalie Hennequin
510(k) history	10 submissions · 10 cleared · 2012-2025

REGULATORY CONSULTANT

Consulting firm	**Clariance, Inc.**
Contact	Magalie Hennequin

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