FDA 510(k) Premarket Notification

K240872 Erisma® Deformity Spinal System

CLEARED

Apr 26, 2024
28 days to decision

K240872 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k240872/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 29, 2024
Decision date	Apr 26, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Erisma® Lp Spinal Fixation System

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k240872/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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