FDA 510(k) Premarket Notification

K231807 primaLOK™ SP Interspinous Fusion System

CLEARED

Aug 15, 2023
56 days to decision

K231807 · Product code: **PEK** · Orthopedic
Source: https://www.510kdatabase.net/k231807/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Jun 20, 2023
Decision date	Aug 15, 2023
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Wenzel Spine, Inc.**
Location	Austin, TX, US
Contact	William Wilson
510(k) history	6 submissions · 6 cleared · 2013-2025