FDA 510(k) Premarket Notification

CLEARED

K223719 Paeon Anterior Cervical Plate System, Elatus Lumbar Plate System

Jan 11, 2023
30 days to decision

K223719 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k223719/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Dec 12, 2022
Decision date	Jan 11, 2023
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aegis Spine, Inc.**
Location	Englewood, CO, US
Contact	Kihyang Kim
510(k) history	5 submissions · 5 cleared · 2021-2023