FDA 510(k) Premarket Notification

K210325 APOLLO Anterior Cervical Plate (ACP) System

CLEARED

Mar 23, 2021
47 days to decision

K210325 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k210325/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 4, 2021
Decision date	Mar 23, 2021
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aurora Spine, Inc.**
Location	Washington, DC, US
Contact	Laszlo Garamszegi
510(k) history	7 submissions · 7 cleared · 2014-2022

REGULATORY CONSULTANT

Consulting firm	**Watershed Idea Foundry**
Contact	Jeffrey Brittan

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