FDA 510(k) Premarket Notification

K210521 DEXA-C Cervical Interbody System

CLEARED

Aug 2, 2021
160 days to decision

K210521 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k210521/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 23, 2021
Decision date	Aug 2, 2021
Days to decision	160 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