FDA 510(k) Premarket Notification

K230993 CODA™ Anterior Cervical Plate System

CLEARED

Jun 20, 2023
75 days to decision

K230993 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k230993/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Apr 6, 2023
Decision date	Jun 20, 2023
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pioneer Surgical Technology, Inc D.B.A Resolve Surgical Tech**
Location	Marquette, MI, US
Contact	Alicia Kaufman
510(k) history	2 submissions · 2 cleared · 2022-2023