FDA 510(k) Premarket Notification

K231766 Skyway Anterior Cervical Plate System

CLEARED

Sep 12, 2023
88 days to decision

K231766 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k231766/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jun 16, 2023
Decision date	Sep 12, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kyocera Medical Technologies Inc. (KMTI)**
Location	Redlands, CA, US
Contact	Joey Thompson
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	Nathan Wright

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