

K250486 Skyway Anterior Cervical Plate SystemApr 10, 2025
50 days to decisionK250486 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k250486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 19, 2025
Decision date	Apr 10, 2025
Days to decision	50 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](https://accessdata.fda.gov)

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