

K231766 Skyway Anterior Cervical Plate SystemSep 12, 2023
88 days to decisionK231766 · 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](https://accessdata.fda.gov)

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