

K240935 ARENAL Anterior Cervical Plate SystemMay 17, 2024
42 days to decisionK240935 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k240935/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Appliance, Fixation, Spinal Intervertebral Body (KWQ) |
| Date received | Apr 5, 2024 |
| Decision date | May 17, 2024 |
| Days to decision | 42 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Effortmed, LLC |
| Location | Coral Springs, FL, US |
| Contact | Steven Brown |
| 510(k) history | 3 submissions · 3 cleared · 2024-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|-----------------------------------|
| Consulting firm | The OrthoMedix Group, Inc. |
| Contact | J.D. Webb |

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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