

K212405 EMERGE™ Anterior Cervical Plate SystemSep 30, 2021
59 days to decisionK212405 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k212405/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Appliance, Fixation, Spinal Intervertebral Body (KWQ) |
| Date received | Aug 2, 2021 |
| Decision date | Sep 30, 2021 |
| Days to decision | 59 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Evolution Spine |
| Location | Dallas, TX, US |
| Contact | Todd Wallenstein |
| Website | https://evolutionsspine.com |
| 510(k) history | 8 submissions · 8 cleared · 2021-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212405/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026