

K122497 ASFORA ANTERIOR CERVICAL PLATE SYSTEM, ONE LEVEL, 14MM ASFORA ANTERIOR CERVICAL PLATE SYSTEM, ONE LEVEL, 16MMOct 15, 2012
60 days to decisionK122497 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k122497/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Appliance, Fixation, Spinal Intervertebral Body (KWQ) |
| Date received | Aug 16, 2012 |
| Decision date | Oct 15, 2012 |
| Days to decision | 60 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Medical Design, LLC |
| Location | Brandon, SD, US |
| Contact | KRISTI VONDRA |
| 510(k) history | 3 submissions · 3 cleared · 2002-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122497/> 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 18, 2026