

**K190166 TriMed Nitinol Staple System**Jul 1, 2019  
151 days to decisionK190166 · Product code: **JDR** · Orthopedic  
Source: <https://www.510kdatabase.net/k190166/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Staple, Fixation, Bone (JDR)       |
| Date received         | Jan 31, 2019                       |
| Decision date         | Jul 1, 2019                        |
| Days to decision      | 151 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>TriMed, Inc.</b>                     |
| Location       | Saugus, CA, US                          |
| Contact        | David Medoff                            |
| 510(k) history | 36 submissions · 36 cleared · 2005-2026 |

**REGULATORY CONSULTANT**

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|-----------------|---------------------|
| Consulting firm | <b>Jean Asquith</b> |
| Contact         | Jean Asquith        |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190166/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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