

K142148 ORTHOHELIX STAPLE SYSTEMAug 21, 2014
16 days to decisionK142148 · Product code: **JDR** · Orthopedic
Source: <https://www.510kdatabase.net/k142148/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Staple, Fixation, Bone (JDR) |
| Date received | Aug 5, 2014 |
| Decision date | Aug 21, 2014 |
| Days to decision | 16 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Orthohelix Surgical Designs, Inc. |
| Location | Cleveland, OH, US |
| Contact | BRIAN HOCKETT |
| 510(k) history | 25 submissions · 25 cleared · 2005-2014 |

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