

**K212731 Circul8 Pro**Nov 15, 2021  
77 days to decisionK212731 · Product code: **JOW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k212731/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Sleeve, Limb, Compressible (JOW)   |
| Date received         | Aug 30, 2021                       |
| Decision date         | Nov 15, 2021                       |
| Days to decision      | 77 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Ortho8, Inc.</b>                   |
| Location       | Rocklin, CA, US                       |
| Contact        | Nordeen Taylor                        |
| 510(k) history | 3 submissions · 3 cleared · 2021-2022 |

**REGULATORY CONSULTANT**

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|-----------------|----------------------------|
| Consulting firm | <b>Medtech Review, LLC</b> |
| Contact         | John Beasley               |

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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