

**K203334 The Citrefix Knotless Suture Anchor**Feb 5, 2021  
85 days to decisionK203334 · Product code: **MAI** · Orthopedic  
Source: <https://www.510kdatabase.net/k203334/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | Fastener, Fixation, Biodegradable, Soft Tissue (MAI) |
| Date received         | Nov 12, 2020   |
| Decision date         | Feb 5, 2021  |
| Days to decision      | 85 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Acuitive Technologies, Inc.</b>    |
| Location       | Alendale, NJ, US                      |
| Contact        | Matthew Poggie                        |
| 510(k) history | 6 submissions · 6 cleared · 2021-2024 |

**REGULATORY CONSULTANT**

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|-----------------|----------------------|
| Consulting firm | <b>BioVera, Inc.</b> |
| Contact         | Robert A Poggie      |

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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