

**K212912 OneFix Biocomposite Anchors, OneFix Biocomposite Small Anchors, OneFix All Suture Anchors, OneFix Interference Screws, OneFix Cannula System**Nov 4, 2021  
52 days to decisionK212912 · Product code: **MAI** · Orthopedic  
Source: <https://www.510kdatabase.net/k212912/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Sep 13, 2021
Decision date	Nov 4, 2021
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>B-One Ortho, Corp.</b>
Location	Cedar Knolls, NJ, US
Contact	Allison Gecik
510(k) history	12 submissions · 12 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212912/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026