

**K213018 Auxilock GFS Mini, GFS II Large, and GFS Ultimate**Nov 18, 2022  
424 days to decisionK213018 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k213018/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 20, 2021
Decision date	Nov 18, 2022
Days to decision	424 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Auxein Medical Private Limited</b>
Location	Sonipat, IN
Contact	Rahul Luthra
510(k) history	12 submissions · 12 cleared · 2020-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213018/> 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