

**K233601 Fixone Meniscal Repair**Aug 2, 2024  
267 days to decisionK233601 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k233601/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Nov 9, 2023
Decision date	Aug 2, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aju Pharm Co., Ltd.</b>
Location	Seongnam-Si, KR
Contact	Kwon Mingyeong
510(k) history	10 submissions · 10 cleared · 2017-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Plusglobal</b>
Contact	Peter Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233601/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026