

K222423 Fixone All Suture AnchorMar 23, 2023
224 days to decisionK222423 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k222423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Aug 11, 2022
Decision date	Mar 23, 2023
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aju Pharm Co., Ltd.
Location	Seongnam-Si, KR
Contact	Gun Tak Lee
510(k) history	10 submissions · 10 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	Plusglobal
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)

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