

K192032 Fixone Biocomposite Small AnchorMar 3, 2020
217 days to decisionK192032 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k192032/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Jul 30, 2019
Decision date	Mar 3, 2020
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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