

K192484 Fixone Biocomposite AnchorMar 11, 2020
183 days to decisionK192484 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k192484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Sep 10, 2019
Decision date	Mar 11, 2020
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192484/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026