

K171299 Fixone Biocomposite AnchorAug 24, 2017
113 days to decisionK171299 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k171299/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	May 3, 2017
Decision date	Aug 24, 2017
Days to decision	113 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

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