

K192709 Fixone All Suture AnchorDec 15, 2020
445 days to decisionK192709 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k192709/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 27, 2019
Decision date	Dec 15, 2020
Days to decision	445 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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