

K193497 Fixone Biocomposite Interference ScrewJan 5, 2021
385 days to decisionK193497 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k193497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Dec 17, 2019
Decision date	Jan 5, 2021
Days to decision	385 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	Kim Joong Kil
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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193497/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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