FDA 510(k) Premarket Notification

K193497 Fixone Biocomposite Interference Screw

CLEARED

Jan 5, 2021
385 days to decision

K193497 · 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