FDA 510(k) Premarket Notification

K230892 Fixone Biocomposite Anchor

CLEARED

Jun 9, 2023
70 days to decision

K230892 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k230892/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Mar 31, 2023
Decision date	Jun 9, 2023
Days to decision	70 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	Kwon Mingyeong
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