FDA 510(k) Premarket Notification

CLEARED

K231326 Fix2Lock(Biocomposite medial, lateral, Biocombi Self Punching)

May 31, 2023
23 days to decision

K231326 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k231326/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	May 8, 2023
Decision date	May 31, 2023
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osteonic Co., Ltd.**
Location	Seoul, KR
Contact	Da Kyung Ham
Website	https://www.osteonic.com
510(k) history	20 submissions · 20 cleared · 2015-2026

Osteonic Co., Ltd. is a Seoul-based medical device manufacturer specializing in bone implant and reconstructive implant systems. The company designs metal and biodegradable composite-based products for surgical applications. Osteonic has received FDA 510(k) clearances from total submissions since 2015. The company's cleared devices span orthopedic, neurology, and dental categories. Most recent clearance occurred in 2026, confirming active regulatory engagement and current market presence. The company's product portfolio includes orthopedic plating systems, neuro plating s...

REGULATORY CONSULTANT

Consulting firm	**Wise Company, Inc.**
Contact	Sanglok Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov