FDA 510(k) Premarket Notification

K202663 Suture Wing

CLEARED

Jun 7, 2021
266 days to decision

K202663 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k202663/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 14, 2020
Decision date	Jun 7, 2021
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osteonic Co., Ltd.**
Location	Seoul, KR
Contact	Dakyung 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