FDA 510(k) Premarket Notification

K202883 Sterile bone screw (PEEK ACL screw)

CLEARED

Nov 25, 2020
58 days to decision

K202883 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k202883/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 28, 2020
Decision date	Nov 25, 2020
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osteonic Co., Ltd.**
Location	Seoul, KR
Contact	Sungmoo Hwang
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202883/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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