

K190915 OsteoFab Suture AnchorsJul 3, 2019
85 days to decisionK190915 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k190915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Apr 9, 2019
Decision date	Jul 3, 2019
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oxford Performance Materials, Inc.
Location	South Windsor, CT, US
Contact	Andrus Maandi
510(k) history	3 submissions · 3 cleared · 2016-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190915/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026