

K190526 High V+ Bone Cement, CarboClear® Fenestrated Pedicle ScrewsSep 19, 2019
199 days to decisionK190526 · Product code: **PML** · Orthopedic
Source: <https://www.510kdatabase.net/k190526/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Posterior Screw Augmentation (PML)
Date received	Mar 4, 2019
Decision date	Sep 19, 2019
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CarboFix Orthopedics , Ltd.
Location	Herzliya, IL
Contact	Hila Wachsler-Avrahami
510(k) history	32 submissions · 32 cleared · 2011-2026

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