

K193378 CarboClear Lumbar Cage SystemMar 2, 2020
88 days to decisionK193378 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k193378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 5, 2019
Decision date	Mar 2, 2020
Days to decision	88 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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