

**K203683 CarboClear Lumbar Cage System**Jan 15, 2021  
29 days to decisionK203683 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k203683/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 17, 2020
Decision date	Jan 15, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carbofix Orthpedics , Ltd.</b>
Location	Herzliya, IL
Contact	Hila Wachsler-Avrahami
510(k) history	2 submissions · 2 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203683/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026